

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

AMAL EGHNAYEM, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:13-cv-07965

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(Daubert Motions)

The following motions have been brought by the defendant, Boston Scientific Corporation (“BSC”): (1) Motion to Exclude the Testimony of Richard W. Trepeta, M.D. [Docket 86]; (2) Motion to Exclude the Testimony of Dr. Michael Thomas Margolis [Docket 88]; (3) Motion to Exclude the Testimony of Thomas H. Barker, Ph.D. [Docket 90]; (4) Motion to Exclude the Testimony of Jimmy W. Mays, Ph.D. and Samuel P. Gido, Ph.D. [Docket 92]; (5) Motion to Exclude the Opinions and Testimony of Emery Salom, M.D., FACOG [Docket 94]; (6) Motion to Exclude the Testimony of Dr. Peggy Pence, Ph.D. [Docket 96]; (7) Motion to Exclude the Testimony of Dr. Mark Slack [Docket 98]; (8) Motion for Leave to File Supplemental Brief to Its Motion to Exclude Testimony of Dr. Mark Slack [Docket 147]; (9) Motion to Exclude the Testimony of Dr. Raybon [Docket 100]; (10) Motion to Exclude the Testimony of Linda Kiley, M.D. [Docket 102]; (11) Motion to Exclude the Testimony of Vladimir Iakovlev, M.D. [Docket 104]; (12) Motion to Exclude the Testimony of Konstantin

Walmsley, M.D. [Docket 109]; and (13) Motion to Exclude the Opinions and Testimony of Jorge Pando, M.D. [Docket 155].

The following motions have been brought by the plaintiffs: (1) Motion to Exclude the Testimony of Stephen H. Spiegelberg, Ph.D. [Docket 111]; (2) Motion to Exclude the Testimony of Stephen Badylak, M.D. [Docket 113]; (3) Motion to Exclude the Testimony of Matthew F. Davies, M.D. [Docket 115]; (4) Motion to Exclude the Testimony of Christine L. Brauer, Ph.D. [Docket 117]; (5) Motion to Exclude the Testimony of Gary L. Winn, Ph.D. [Docket 119].

For the reasons explained below, the defendant's motion with respect to Dr. Trepeta [Docket 86] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Margolis [Docket 88] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Barker [Docket 90] is **GRANTED**. The defendant's motion with respect to Drs. Mays and Gido [Docket 92] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Salom [Docket 94] is **DENIED**. The defendant's motion with respect to Dr. Pence [Docket 96] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motions with regard to Dr. Slack [Dockets 98 and 147] are **GRANTED** and **DENIED**, respectively. The defendant's motion with respect to Dr. Raybon [Docket 100] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Kiley [Docket 102] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with regard to Dr. Iakovlev [Docket 104] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with regard to Dr. Walmsley [Docket 109] is **DENIED IN PART** and **DENIED AS MOOT**. The defendant's motion with respect to Dr. Pando [Docket 155] is **GRANTED**.

The plaintiffs' motion with regard to Dr. Spiegelberg [Docket 111] is **GRANTED IN PART** and **RESERVED IN PART**. The plaintiffs' motion with respect to Dr. Badylak [Docket 113] is **GRANTED IN PART** and **RESERVED IN PART**. The plaintiff's motion with regard to Dr. Davies [Docket 115] is **DENIED**. The plaintiffs' motion with regard to Dr. Brauer [Docket 117] is **GRANTED**. The plaintiffs' motion with regard to Dr. Winn [Docket 119] is **GRANTED**.

I. Background

This consolidated case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are over 60,000 cases currently pending, over 13,000 of which are in the Boston Scientific Corporation MDL, MDL 2326. In this particular case, the four plaintiffs were surgically implanted with the Pinnacle Pelvic Floor Repair Kit ("the Pinnacle"), a mesh product manufactured by BSC to treat POP. (*See* Pretrial Order # 91 [Docket 10], at 1–2).¹ All of the plaintiffs received their surgeries in Florida. The plaintiffs claim that as a result of implantation of the Pinnacle, they have experienced "erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain." (*Id.* at 3 (quoting the master complaint)). The plaintiffs allege negligence, design defect, manufacturing defect, failure to warn, breach of express warranty, breach of implied warranty, and punitive damages. (*Id.* at 1–2). The parties

¹ I originally consolidated the cases of five plaintiffs implanted with the Pinnacle. (*See* Pretrial Order # 91 [Docket 10] (naming Eghnayem, Dotres, Nunez, Dubois-Jean, and Betancourt as consolidated plaintiffs)). Four plaintiffs now remain in this action. (*See* Order [Docket 35] (removing Dubois-Jean from the consolidated pool)).

have retained experts to render opinions regarding the elements of these causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions and testimony pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is “qualified . . . by knowledge, skill, experience, training, or education,” and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) “based upon sufficient facts or data”; and (3) “the product of reliable principles and methods” that (4) have been reliably applied “to the facts of the case.” Fed. R. Evid. 702. The U.S. Supreme Court established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to “prove” anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Id.*

The district court is the gatekeeper.² It is an important role: “[E]xpert witnesses have the potential to be both powerful and quite misleading[;]” the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I “need not determine

² With more than 60,000 cases related to surgical mesh products currently pending before me, this gatekeeper role takes on extraordinary significance. Each of my evidentiary determinations carries substantial weight with the remaining surgical mesh cases. Regardless, while I am cognizant of the subsequent implications of my rulings in these cases, I am limited to the record and the arguments of counsel.

that the proffered expert testimony is irrefutable or certainly correct”—“[a]s with all other admissible evidence, expert testimony is subject to testing by ‘vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that “[a]ll *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful”).

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We agree with the Solicitor General that ‘[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.’”) (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* further explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (internal citations and quotation marks omitted).

Finally, in several of the instant *Daubert* motions, a specific scientific methodology comes into play, dealing with differential diagnoses or etiologies. “Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.” *Westberry*, 178 F.3d at 262. The Fourth Circuit has stated that:

A reliable differential diagnosis typically, though not invariably, is performed after “physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests,” and generally is accomplished by determining the possible causes for the patient’s symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Id. A reliable differential diagnosis passes scrutiny under *Daubert*. An unreliable differential diagnosis is another matter:

A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation. However, “[a] medical expert’s causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff’s illness.” The alternative causes suggested by a defendant “affect the weight that the jury should give the expert’s testimony and not the admissibility of that testimony,” unless the expert can offer “no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause.”

Id. at 265–66 (internal citations omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the “the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.” *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

Before I review these motions, I begin by addressing three arguments that apply to many of the parties’ *Daubert* objections. First, as I have maintained throughout these MDLs, I will not permit the parties to use experts to usurp the jury’s fact-finding function by allowing an expert to testify as to a party’s state of mind or on whether a party acted reasonably. *See, e.g., Huskey v. Ethicon, Inc.*, 2:12-cv-05201, 2014 WL 3362264, at *3 (S.D. W. Va. July 8, 2014); *Lewis, et al. v. Ethicon, Inc.*, 2:12-cv-4301, 2014 WL 186872, at *6, *21 (S.D. W. Va. Jan. 15, 2014); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611, 629 (S.D. W. Va. 2013). Although an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party’s knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.

Second, “opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.” *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). I have diligently applied this rule to previous expert testimony, and I continue to adhere to it in this case. I will not parse the expert reports and depositions of each expert in relation to these same objections. I trust that able counsel in this matter will tailor expert testimony at trial accordingly.

Last, with respect to the arguments that certain experts' testimony is litigation driven, I note that an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify that expert's exclusion. *See Daubert v. Merrell Dow Pharm., Inc.* ("Daubert II"), 43 F.3d 1311, 1317 (9th Cir. 1995) ("That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture."). This concern, however, does have a role in applying *Daubert*. *See Hoffman v. Monsanto Co.*, No. 2:05-cv-00418, 2007 WL 2984692, at *3 (S.D. W. Va. Oct. 11, 2007) (considering in the *Daubert* analysis "[w]hether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying" (quoting Fed. R. Evid. 702 advisory committee's note)). In sum, I will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable. But I will consider the independence of an expert's testimony as evidence that his "research comports with the dictates of good science." *Daubert II*, 43 F.3d at 1317. Having addressed these universal objections, I now turn to BSC's *Daubert* motions.

III. BSC's *Daubert* Motions

In this case, BSC seeks to limit or exclude certain opinion testimony of Dr. Richard W. Trepeta, Dr. Michael Thomas Margolis, Dr. Thomas H. Barker, Drs. Jimmy W. Mays and Samuel P. Gido, Dr. Emery Salom, Dr. Peggy Pence, Dr. Mark Slack, Dr. R. Brian Raybon, Dr. Linda Kiley, Dr. Vladimir Iakovlev, Dr. Konstantin Walmsley, and Dr. Jorge Pando.

A. Motion to Exclude the Testimony of Richard W. Trepeta, M.D.

In this case, the plaintiffs offer Dr. Trepeta to testify as an expert witness on the general pathology of vaginal mesh implantation (*see generally* Trepeta General Report [Docket 87-1]) and on the specific pathology of Plaintiffs Nunez (*see generally* Trepeta Report re: Nunez [Docket 87-2]; Trepeta Report re: Betancourt [Docket 87-3]). Among other things, Dr. Trepeta is a board-certified pathologist and a Fellow with the College of American Pathologists and the International Society for the Study of Vulvovaginal Disease. As part of his fellowship, he “establishes criteria and terminology for the diagnosis of vulvar and vaginal diseases.” (Trepeta General Report [Docket 87-1], at 2). Dr. Trepeta also examines vulvar–vaginal pathology samples through his private practice. (*Id.*).

BSC moves to exclude Dr. Trepeta as an expert witness, raising two primary objections: (1) Dr. Trepeta is not qualified to opine on the properties of polypropylene mesh or the clinical responses to mesh implants; and (2) Dr. Trepeta’s opinions are unreliable, irrelevant, and not helpful to the jury. (*See generally* BSC’s Mem. in Supp. of its Mot. to Exclude Richard W. Trepeta (“BSC’s Mem. re: Trepeta”) [Docket 87]). As further explained below, I **GRANT IN PART** and **DENY IN PART** BSC’s Motion to Exclude Dr. Trepeta [Docket 86].

1. Dr. Trepeta’s Qualifications

BSC begins by contending that Dr. Trepeta’s background in pathology does not qualify him under Federal Rule of Evidence 702 to render the opinions he sets forth in his expert reports on the properties of polypropylene and the human clinical response to polypropylene implants.

a. Properties of Polypropylene Mesh

In his general report, Dr. Trepeta opines about mesh degradation, mesh contraction, and mesh migration. He states that “[d]egradation occurs as either fragmentation of the mesh or

oxidation [of the mesh] release[s] chemical components from the mesh into surrounding tissues,” and “[m]esh contraction and shrinkage cause the mesh to be significantly decreased in its physical size.” (Trepeta General Report [Docket 87-1], at 5). BSC asserts that Dr. Trepeta is not qualified to put forth these opinions because he is not a material scientist, biochemist, or biomedical engineer. (*See* Trepeta Dep. [Docket 87-4], at 100:20–101:1). Furthermore, he has no training in polymer science or biomedical engineering and has not performed mechanical or chemical testing of mesh products. (*See id.* at 101:2–11).

In *Sanchez, et al. v. Boston Scientific Corp.*, I considered this argument and disagreed with BSC:

In making [its] argument, however, BSC downplays Dr. Trepeta’s knowledge, training, and experience as a clinical pathologist. In general, a clinical pathologist “will be knowledgeable in the areas of chemistry, hematology, microbiology, . . . serology, immunology, and other special laboratory studies.” 33 Am. Jur. *Trials* § 17 (1986); *see also* Coll. of Am. Pathologists, *CAP Fact Sheet*, <http://www.cap.org> (last visited Sept. 22, 2014) (“[Clinical pathologists] are involved in a broad range of disciplines, including surgical pathology, cytopathology, . . . clinical chemistry, microbiology, immunopathology, and hematology.”). Dr. Trepeta’s thirty years’ experience as a clinical pathologist therefore demonstrates sufficient knowledge to provide expert testimony about the chemistry and surgical pathology of materials like transvaginal mesh. Moreover, Dr. Trepeta has knowledge of and experience with pelvic mesh explants in particular, having examined fifty explant samples over the past five years. (*See* Trepeta General Report [Docket 86-1], at 2). According to Dr. Trepeta, by examining the mesh explants under a microscope, he has witnessed the polypropylene’s chemical changes. (*See* Trepeta Dep. [Docket 110-3], at 217:14–19). Given Dr. Trepeta’s knowledge and experience as an anatomical and clinical pathologist, I **FIND** that he is qualified to testify about mesh degradation, mesh shrinkage, and mesh migration, and I therefore **DENY** BSC’s motion in this respect.

No. 2:12-cv-05762, 2014 WL 4851989, at *20 (S.D. W. Va. Sept. 29, 2014). I **ADOPT** this holding here.

b. The Human Clinical Response to Polypropylene Mesh

Dr. Trepeta also opines that the “human body’s pathological response to implantation of polypropylene mesh as well as the inherent physical properties of the mesh cause permanent injuries resulting in distortion of the pelvic architecture, sexual dysfunction, persistent pain, scarring, and alteration of bowel and bladder function.” (Trepeta General Report [Docket 87-1], at 6). BSC contends that Dr. Trepeta is not qualified to present this opinion because Dr. Trepeta does not treat patients for these conditions and has limited familiarity with the symptoms of stress urinary incontinence and pelvic organ prolapse. (*See* Trepeta Dep. [Docket 87-4], at 109:21–23). In short, BSC argues that Dr. Trepeta is not a gynecologist, obstetrician, urogynecologist, or a surgeon, and as a result, Dr. Trepeta’s opinions about the clinical response to mesh should be excluded.

In *Sanchez*, I addressed this argument and held:

Dr. Trepeta’s extensive experience and knowledge in the field of pathology qualify him to submit these opinions. Part of pathology involves reaching a diagnosis through “clinical and pathologic correlation.” [(*See* Trepeta Dep. [Docket 86-3], at 11:10–14)]. Dr. Trepeta frequently engages in this process by providing clinical consultations to physicians, which require him to examine clinical information (through specimens, reports, or physician findings) and reach a pathologic diagnosis about a patient. (*See id.*). Dr. Trepeta applied this pathologic process in reaching his conclusions about the human clinical responses to polypropylene vaginal mesh. He examined fifty pathology samples from mesh removals and opines that he observed injuries “consistent with the pathological process of tissue response and/or injury due to polypropylene.” (Trepeta General Report [Docket 86-1], at 2). He also compared medical literature to these observations and concluded that his pathological findings “are well described in the published literature.” (*Id.*). Dr. Trepeta’s understanding and application of the pathologic process qualify him to opine on the causal relationship between transvaginal mesh implantation and tissue response. Therefore, I **DENY** BSC’s motion on this point.

2014 WL 4851989, at *20 (footnote omitted). I **ADOPT** this holding here.

2. The Reliability and Relevance of Dr. Trepeta’s Opinions

Next, BSC raises several objections to the reliability and relevancy of Dr. Trepeta's opinion testimony. I addressed each of these objections in *Sanchez* and consequently rely on *Sanchez* to explicate my conclusions here.

a. Reliability of Dr. Trepeta's Methodology in Formulating His Opinions

BSC contends that Dr. Trepeta's method of using pathology reports to formulate his opinions is unreliable. Dr. Trepeta used various resources to reach his expert opinion. First, Dr. Trepeta has studied over fifty mesh explant samples in his private practice. Dr. Trepeta received these samples from physicians about once a month over the past five years. (*See* Trepeta Dep. [Docket 87-4], at 71:10–12). He examined these samples under a microscope, identified any abnormalities, and concluded that the samples presented injuries “consistent with the pathological process of tissue response and/or injury due to polypropylene.” (*See* Trepeta General Report [Docket 87-1], at 2). Second, Dr. Trepeta studied the medical literature on mesh implantation and determined that his pathological findings correspond with the published research on mesh erosion and exposure in the vaginal wall. (*See id.* at 2–3). Third, Dr. Trepeta reviewed twenty-four pathology reports that he received from the plaintiffs' counsel and ascertained that “the pathology reports of excised Boston Scientific Products . . . are consistent” with the acute, sub-acute, and chronic categories of the disease process. (*Id.* at 4).

As I held in *Sanchez*:

BSC's strongest objection to Dr. Trepeta's methodology focuses on this third source of information. BSC argues that the twenty-four pathology reports were unreliable because: they were “hand-selected by Plaintiffs' counsel”; Dr. Trepeta only relied on seventeen of the twenty-four reports; and Dr. Trepeta did not review the medical records of any of the probed patients. (BSC's Mem. re: Trepeta [Docket 235], at 11–12). The plaintiffs respond that these pathology reports only supplemented Dr. Trepeta's opinion and that the main thrust of Dr. Trepeta's opinion comes from his review of fifty mesh explants over the past five

years and from his study of medical literature. Moreover, the plaintiffs argue that BSC's chosen expert, Dr. Badylak, agreed that review of pathology reports of vaginal tissue taken from polypropylene explants is an accepted method for reaching a pathologic conclusion on tissue response to polypropylene. (*See* Pls.' Resp. in Opp'n to Def.'s Mot. to Exclude Dr. Trepeta [Docket 110], at 13).

The fact that each side's pathologist accepts this practice suggests that it is accepted by the general community of pathologists. *See Daubert*, 509 U.S. at 594 ("Widespread acceptance can be an important factor in ruling particular evidence admissible . . ."). But Dr. Trepeta's review of the pathology reports still has a fatal deficiency in that it lacked standards to govern the process of selecting the sample of pathology reports to be evaluated. *See id.* (listing as a factor in evaluating an expert's opinion the "existence and maintenance of standards controlling the technique's operation"). The plaintiffs do not explain how or why they chose these twenty-four reports for Dr. Trepeta's review, and without such an explanation, I have no way of assessing the potential rate of error or the presence of bias. *See id.* (stating that the "court ordinarily should consider the potential rate of error"). I confronted a similar situation in *Lewis, et al. v Ethicon, Inc.* and excluded the expert opinion on hand-selected explant samples because "[t]here are no assurances that [plaintiffs' counsel] did not opportunistically choose samples while ignoring others that might have weakened or disproved [the expert's] theories." No. 2:12-cv-4301, 2014 WL 186872, at *8 (S.D. W. Va. Jan 15, 2014). Here, I similarly have no way to ensure that the plaintiffs' counsel did not provide Dr. Trepeta with only those pathology reports that tended to strengthen, rather than refute, Dr. Trepeta's opinions. Accordingly, Dr. Trepeta's opinions derived from his review of the twenty-four pathology reports are **EXCLUDED**.

2014 WL 4851989, at *22. I **ADOPT** this holding, accepting Dr. Trepeta's opinions as reliable apart from those opinions based on his review of the twenty-four pathology reports.

b. Litigation Driven Opinions

BSC also argues Dr. Trepeta's opinions are unreliable because they are litigation-driven. Specifically, BSC asserts that Dr. Trepeta's "familiarity with the literature on polypropylene mesh comes only from his research and reading in connection with this litigation." (BSC's Mem. re: Trepeta [Docket 87], at 13). As in *Sanchez*, I disagree. Dr. Trepeta has largely based his opinions on his professional experience with mesh pathology samples examined during his

practice. (Trepeta General Report [Docket 87-1], at 2). In addition, he testified that he has “looked at mesh removed from the bodies of female vaginal walls under the microscope” and has seen degradation. (Trepeta Dep. [Docket 131-4], at 217:14–19). These activities occurred outside of this litigation. Thus, I **FIND** that Dr. Trepeta’s opinions are not litigation-driven and **DENY** BSC’s motion on this point.

c. Dr. Trepeta’s Specific Causation Opinion

Dr. Trepeta also offers a specific causation opinion concerning Ms. Nunez and Ms. Betancourt. For both plaintiffs, Dr. Trepeta opines that their

symptoms of pain, discharge, infection, dyspareunia, mesh exposure, resulting diagnoses, and medical treatment for vaginal and pelvic floor complications are all directly attributable to the implantation of polypropylene surgical mesh in the Pinnacle Pelvic Floor Repair surgical mesh. . . . My personal experience as a pathologist, with special training and focus on pathology of the vagina, as well as my knowledge and training, has shown complications directly as effect of tissue response to polypropylene implant. . . .

(Trepeta Report re: Nunez [Docket 87-2], at 5; Trepeta Report re: Betancourt [Docket 87-3], at 5–6). Dr. Trepeta adds that the “inflammatory response described and documented within the medical records provided by Ms. Nunez [and Ms. Betancourt] are consistent with the chronic phase of mesh implantation.” (Trepeta Report re: Nunez [Docket 87-2], at 5; Trepeta Report re: Betancourt [Docket 87-3], at 5). BSC argues that the specific causation opinions are unreliable because: (1) his general causation opinion is unreliable; and (2) the methodology informing his specific causation opinions “is faulty.” (BSC’s Mem. re: Trepeta [Docket 87], at 14).

Apart from Dr. Trepeta’s review of the twenty-four pathology reports, I concluded that Dr. Trepeta’s general causation opinion was reliable. Therefore, BSC’s first argument fails. BSC next argues that because Dr. Trepeta did not review the plaintiffs’ mesh specimens and instead

based his conclusion on their medical records, his methodology is unreliable. Whether or not a pathologist has reviewed pathology specimens in reaching his opinion does carry weight in determining reliability, but Dr. Trepeta's failure to examine pathology specimens is not determinative here. So long as an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field," he does not necessarily have to perform a physical examination of the patient to offer an expert opinion. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). Here, Dr. Trepeta testified that he often gives pathologic opinions without examining patient specimens or pathology reports. (*See* Trepeta Dep. [Docket 131-4], at 37:11–38:9). Thus, Dr. Trepeta's failure to examine pathology specimens does not automatically render his specific causation opinion unreliable.

I nevertheless find Dr. Trepeta's specific causation opinions unreliable. In addition to not reviewing any of the plaintiffs' pathology specimens, Dr. Trepeta has not conducted a differential diagnosis in reaching his conclusion that Ms. Nunez and Ms. Betancourt's pain resulted from the Pinnacle. In attempt to support a differential diagnosis, the plaintiffs point to Dr. Trepeta's deposition testimony about Ms. Sanchez, a plaintiff in another MDL case, wherein Dr. Trepeta discussed alternative causes of Ms. Sanchez's pain. (*See* Pls.' Resp. in Opp'n to BSC's Mot. to Exclude the Ops. & Test. of Dr. Trepeta [Docket 131], at 19 ("Dr. Trepeta has not been deposed in these two cases. Accordingly, testimony on his methodology in the *Sanchez* case is instructive.")). This testimony is unconvincing. First, in *Sanchez*, I excluded Dr. Trepeta's specific causation testimony about Ms. Sanchez because the differential diagnosis was inadequate. *Sanchez*, 2014 WL 4851989, at *23–24. Second, to qualify as "reliable," a

differential diagnosis must be patient-specific. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999) (explaining that a reliable differential diagnosis “generally is accomplished by determining the possible causes for a *patient’s* symptoms”) (emphasis added). Eliminating causes for Ms. Sanchez, therefore, says nothing about causation for Ms. Nunez and Ms. Betancourt. Disregarding the plaintiffs’ reference to Dr. Trepeta’s testimony about Ms. Sanchez, no reliable differential diagnosis exists for the current plaintiffs.

This ruling corresponds with previous *Daubert* rulings on pathologists. In *Tyree et al. v. Boston Scientific Corp.*, for example, I did not exclude Dr. Trepeta’s specific causation testimony because he had “observed the patient’s slides under a microscope, detected a foreign material, and concluded that the foreign material was polypropylene from the Obtryx sling by applying a process of elimination.” No. 2:12-cv-08633, 2014 WL 5320566, at *18 n.5 (S.D. W. Va. Oct. 17, 2014). Similarly, in the present case, I have not excluded Dr. Iakovlev’s specific causation opinions. Dr. Iakovlev testified that he performed a “morphological differential diagnosis” in preparing his specific causation report for Ms. Eghnayem, which allowed him to rule out alternative causes. (Iakovlev Dep. II [Docket 105-3], at 153). Dr. Trepeta, without reviewing the pathology specimens or performing a differential diagnosis, cannot support his specific causation opinions with a scientific basis. Accordingly, his specific causation opinions on Ms. Nunez and Ms. Betancourt are **EXCLUDED**.

In conclusion, Dr. Trepeta’s general causation opinions satisfy *Daubert*, apart from his opinions based on the pathologic reports selected by the plaintiffs’ counsel for his review, which are **EXCLUDED**. Dr. Trepeta’s specific causation opinions are also **EXCLUDED**. Thus, BSC’s

Motion to Exclude the Opinions and Testimony of Dr. Trepeta is **GRANTED PART** and **DENIED IN PART** [Docket 86].

B. Motion to Exclude the Opinions and Testimony of Michael Thomas Margolis, M.D.³⁴

BSC moves to exclude the opinions and testimony of Michael Thomas Margolis, M.D. Dr. Margolis is a pelvic floor surgeon and urogynecologist. He seeks to offer several opinions regarding polypropylene mesh slings, alternative procedures, and complications associated with mesh products. BSC argues that Dr. Margolis's opinions are unreliable because he failed to consider scientific literature contrary to his opinions and failed to provide any scientific basis for other opinions. (*See* Def. BSC's Mem. of Law in Supp. of Its Mot. to Exclude the Ops. and Test. of Michael Thomas Margolis, M.D. ("BSC's Mem. re: Margolis") [Docket 89], at 1–2). In addition, BSC contends that Dr. Margolis's opinions "either (1) constitute legal opinions, (2) fall outside the scope of his expertise, or (3) consist of speculation regarding Boston Scientific's knowledge, intent and/or state of mind." (*Id.* at 2).

I have previously reviewed the opinion testimony of Dr. Margolis under *Daubert*. *See Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *10–19 (S.D. W. Va. Sept. 29, 2014). The parties in this case assert arguments on the admissibility of Dr. Margolis's expert opinion that I addressed in *Sanchez*. To the extent that there are differences in

³ I ruled in *Sanchez* on *Daubert* motions related to Dr. Margolis, Dr. Trepeta, Drs. Mays and Gido, Dr. Pence, and Dr. Barker. In *Sanchez*, I relied on excerpts of deposition testimony from these experts, most, but not all of which excerpts are attached as exhibits in this case. However, because the depositions cited in *Sanchez* are the same depositions taken on the same date, I have relied on some excerpts from *Sanchez* here.

⁴ On October 6, 2014, the plaintiffs in *Sanchez* filed a Motion for Reconsideration for Dr. Margolis, Dr. Slack, and Dr. Barker. *See Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, [Docket 149]. I denied the motion on October 17, 2014. *See Sanchez*, No. 2:12-cv-05762, [Docket 151]. To the extent the arguments raised in the Motion for Reconsideration related to Dr. Margolis, Dr. Slack, and Dr. Barker overlap or may have been raised in this case, I incorporate my findings here.

fact or exhibits, the court does not find them sufficiently material to this case. Thus, I **ADOPT** my prior ruling on Dr. Margolis as follows, and I **GRANT IN PART** and **DENY IN PART** BSC's motion. I will address additional arguments raised by the parties in this case below.

1. Failure to Consider Contrary Scientific Studies in Forming His Opinions

BSC argues that Dr. Margolis failed to consider scientific studies that were contrary to his opinions without a scientific basis for doing so.

An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (quotations omitted). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*; see also *Abarca v. Franklin Cnty. Water Dist.*, 761 F. Supp. 2d 1007, 1066 n.60 (E.D. Cal. 2011) ("A scientist might well pick data from many different sources to serve as circumstantial evidence for a particular hypothesis, but a reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." (quotations omitted)); *Rimbert v. Eli Lilly & Co.*, No. CIV 06-0874 JCH/LFG, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009) *aff'd*, 647 F.3d 1247 (10th Cir. 2011) ("[A]n expert who chooses to completely ignore significant contrary epidemiological evidence in favor of focusing solely on non-epidemiological studies that support her conclusion engages in a methodology that courts find unreliable.").

a. Opinions Regarding General Complication Rates in Women with Polypropylene Mesh

In particular, BSC challenges Dr. Margolis's general opinions regarding high

complication rates in women with polypropylene mesh products. In *Sanchez*, I cited to Dr. Margolis's deposition testimony, where he explains his belief that studies indicating low single digit complication rates are not accurate because complications are underreported and data is possibly fabricated. *See Sanchez*, 2014 WL 4851989, at *13. I also find that Dr. Margolis's method of "[g]iv[ing] the benefit of the doubt to the patient" is unreliable:

Dr. Margolis explains that, when forming his opinion about the complication rates of a medical procedure, he "give[s] the benefit of the doubt to the patient." ([Margolis Dep. [Docket 132-2],] at 259:7–9). In other words, he "assume[s] the worst-case scenario" and errs on the side of opining as to a higher complication rate to better protect a patient. (*Id.* at 259:11–259:23). Dr. Margolis eventually admits that he has been evaluating the literature and forming his opinions for this case according to that principle as well. (*See id.* at 259:20–260:14). "[G]iv[ing] the benefit of the doubt to the patient" is not a scientific basis for determining the complication rates associated with a mesh device. (*Id.* at 259:8–9).

Sanchez, 2014 WL 4851989, at *14. I **ADOPT** this reasoning here. Dr. Margolis's opinions as to this matter are **EXCLUDED**.

2. Failure to Provide Any Scientific Basis for His Other Opinions

BSC next argues that Dr. Margolis failed to offer any scientific basis for his other opinions and based them solely on his experience.

a. Opinion Concerning the Lack of Sound Scientific Evidence Supporting the Clinical Benefits of Polypropylene Mesh in POP

BSC challenges the reliability of Dr. Margolis's opinions concerning a lack of sound scientific evidence supporting the use of polypropylene mesh in treating POP. (*See BSC's Mem. re: Margolis [Docket 89], at 9–10; Margolis Report [Docket 89-1], at 17*). In support, BSC points to Dr. Margolis's deposition testimony where he contradicts these opinions. For example, BSC cites to his testimony where he admits that there, in fact, are studies supporting the use of polypropylene in POP:

Q: Would you agree that there is data supporting the use, and scientific literature supporting the use, of polypropylene to treat pelvic organ prolapse through a vaginal approach?

A: There is.

(Margolis Dep. [Docket 89-2], at 227:18-22). As I found in *Sanchez* in regards to Dr. Margolis's similar opinions concerning studies supporting the use of polypropylene mesh in treating SUI:

Inconsistent statements of a witness may be addressed on cross-examination. *See Daubert*, 509 U.S. at 596 (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 749 (3d Cir.1994) (“[E]valuating the reliability of scientific methodologies and data does not generally involve assessing the *truthfulness* of the expert witnesses ...”). However, here, Dr. Margolis's inconsistencies seem to directly shed light on the unreliability of his method. Even if Dr. Margolis is stating that there is a lack of *credible* evidence, as the plaintiffs argue, it is still unclear why Dr. Margolis believes these studies lack credibility. As a result, Dr. Margolis's opinions are rendered untrustworthy and unreliable.

Sanchez, 2014 WL 4851989, at *14. I **ADOPT** this reasoning here. Therefore, his opinions as to this matter are **EXCLUDED**.

b. Opinion that the Infection Rate of Polypropylene Mesh is Up to 100%

BSC next challenges Dr. Margolis's opinion that the infection rate of polypropylene mesh is up to 100%. (*See* BSC's Mem. re: Margolis [Docket 89], at 10). As in *Sanchez*, BSC points to a slide presentation that Dr. Margolis has given which cites a study finding infection rates of 0% to 8%. (*See id.*). I addressed this issue in *Sanchez*:

Dr. Margolis's inconsistent presentation does not automatically render his method unreliable. In his report, Dr. Margolis does cite to scientific studies to support his opinion. (*See* Margolis Report [Docket 58-1], at 16) (describing the *Vollebregt* study finding 83.6% of implants contained bacteria during surgical implantation, the *Boulanger* study finding 100% of mesh explants removed in the study due to complications contain bacteria, the *Shah* and *Badlani* study finding infection in mesh patients).

However, as BSC points out, the study which Dr. Margolis cites to support his 100% figure is not directly applicable. The *Boulanger* study did not find that 100% of the mesh systems explanted for the study were infected; the study found that 100% of the mesh systems were contaminated with bacteria. (See Margolis Report [Docket 58-1], at 16; Boulanger et al., *Bacteriological Analysis of Meshes Removed for Complications After Surgical Management of Urinary Incontinence or Pelvic Organ Prolapse*, 19 Int'l Urogynecol J. 827, 827 (2008) [Docket 58-5]). The authors of the *Boulanger* study are not certain that bacteria contamination leads to infection. (See Boulanger, *supra*, at 827, 830) (stating that the “exact role” of bacterial contamination “is not yet clear” and “must be explored by other experimental studies”). They even write that “[i]nfection is a rare complication of retropubic mid-urethral slings (0.7% of cases)” and that their “findings concur with previously published data” on this subject. (Boulanger, *supra*, at 830).

The *Boulanger* study does not support the opinion that there is a 100% infection rate in women who undergo mesh implantation surgery. Therefore, Dr. Margolis’s methodology of basing his opinion on this study is unreliable.

Sanchez, 2014 WL 4851989, at *17. I **ADOPT** this reasoning here. Therefore, his opinion as to this matter is **EXCLUDED**.

c. Opinion on the Percentage or Number of BSC Products Dr. Margolis Has Removed

BSC challenges Dr. Margolis’s opinion on the percentage or number of BSC products that he has removed. (See BSC’s Mem. re: Margolis [Docket 238], at 13). I agreed with BSC in *Sanchez* on this point:

Dr. Margolis testified that he has removed approximately 300 polypropylene mesh and sling products “throughout the last 15 or so years” and gives his “best guess” that 10% to 15% of those were Boston Scientific. (Margolis Dep. [Docket 132-1], at 74:23–76:1). Dr. Margolis explained that “[t]he exact numbers of each [product] I don’t keep track of.” (*Id.* at 74:11–19). When asked how he arrived at that 10% to 15% figure for Boston Scientific products, Dr. Margolis testified that these percentages are just to his “best recollection”:

Q: Have you tried to do a system—did you go back and try to do some kind of systematic count, or are you just doing that from recollection in terms of the percentage of Boston Scientific products?

A: Best recollection.

(*Id.* at 76:13–18). Dr. Margolis testified that he cannot identify the mesh brand by sight after explantation, and he “tr[ies] to get the operative records from the implant” with the product manufacturing information but does not know how often he receives these records for his patients. (*Id.* at 76:2–9, 77:14–78:2).

As a result, BSC argues that Dr. Margolis’s opinion as to the number or percentage of BSC products he has removed is unreliable . . .

Without a reliable basis, Dr. Margolis’s opinions may be erroneous. *See Lewis, et al. v. Ethicon, Inc.*, 2:12-cv-4301, 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014) (excluding expert’s “analyses of the mesh implants” because they were not “controlled for error or bias”). Therefore, his opinions are **EXCLUDED**.

Sanchez, 2014 WL 4851989, at *18. I **ADOPT** this reasoning here. His opinions as to this matter are **EXCLUDED**.

d. Plaintiffs’ Argument Regarding the Daubert Analysis of Dr. Margolis in Lewis

The plaintiffs in this case make an additional argument regarding Dr. Margolis’s expert opinions. The plaintiffs contend that “this Court has already held that neither *Daubert* or Rule 702 require the exclusion of Dr. Margolis’s testimony” in *Lewis* and that, therefore, his testimony should be admitted in this case. (*See* Pls.’ Resp. in Opp’n to BSC’s Mot. to Exclude the Test. of Dr. Margolis (“Pls.’ Resp. re: Margolis”) [Docket 132], at 2 (citing *Lewis v. Ethicon, Inc.*, No. 2:12-cv-04301, 2014 WL 186872, at *15–17) (S. D. W. Va. Jan. 15, 2014)).

However, *Lewis* was a different case involving a different plaintiff, a different defendant, and a different product. Also, in *Lewis*, Dr. Margolis submitted a different expert report which included expert opinions specific to the plaintiff in *Lewis*. As a result, I reject this argument.

e. Plaintiffs’ Argument Regarding Dr. Margolis’s Experience and Kumho Tire

Next, the plaintiffs in this case make an additional argument in response to BSC's contention that Dr. Margolis failed to provide any scientific basis for some of his opinions. (BSC's Mem. re: Margolis [Docket 132], at 2). The plaintiffs argue that Dr. Margolis's experience alone is enough basis for his opinions and quote the Supreme Court in *Kumho Tire* stating "an expert might draw a conclusion from . . . extensive and specialized experience." (Pls. Resp. re: Margolis [Docket 132], at 2, 10 (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 156 (1999))).

However, "[p]roposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds' based on what is known." *Daubert*, 509 U.S. at 590. Dr. Margolis writes that he "considered the scientific literature" in forming his opinions, (*see* Margolis Report [Docket 89-1], at 5), yet, as I discuss in *Sanchez*, he is unable to provide scientific support for some of his opinions. *See Sanchez*, 2014 WL 4851989, at *14–18. Even though Dr. Margolis has experience, he must still base his opinions on a reliable, scientific method. *See Daubert*, 509 U.S. at 590 ("[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method."). The plaintiffs' argument is unavailing.

3. Offering Opinions Outside Area of Expertise

BSC argues that several of Dr. Margolis's opinions should be excluded because they are outside his area of expertise. (*See* BSC Mem. re: Margolis [Docket 89], at 12). In particular, BSC challenges Dr. Margolis's opinions as to: "biomaterials, adequate pore size, adequate weight of polypropylene, polypropylene degradation, biocompatibility of polypropylene, medical device design and development, and marketing." (*Id.* (internal citations omitted)). As in *Sanchez*, the plaintiffs conceded that Dr. Margolis will not be offering these opinions at trial. (*See* Pls.' Resp.

re: Margolis [Docket 132], at 13). Therefore, this aspect of BSC's motion is **DENIED AS MOOT**.

4. Impermissible Expert Opinions As To BSC's State of Mind

BSC also argues that Dr. Margolis seeks to offer testimony as to BSC's state of mind, knowledge, and intent during product development. As I explained in *Sanchez*, expert testimony about a defendant company's state of mind is impermissible. In *Lewis*, I excluded state of mind testimony of Dr. Margolis because "he is not qualified ... to opine on Ethicon's state of mind or knowledge." *Lewis*, 2014 WL 186872, at * 15. The plaintiffs concede that Dr. Margolis will not be offering these opinions at trial. (*See* Pls.' Resp. re: Margolis [Docket 132], at 13). Therefore, this aspect of BSC's motion is **DENIED AS MOOT**.

Therefore, I **GRANT IN PART** and **DENY IN PART** BSC's motion regarding Dr. Margolis [Docket 88].

C. Motion to Exclude the Testimony of Thomas H. Barker, Ph.D.

BSC moves to exclude the opinions and testimony of Thomas H. Barker, Ph.D. Dr. Barker is a biomedical engineer who seeks to opine as to the behavior of polypropylene mesh inside of the human body. (*See* Barker Report [Docket 91-1], at 1, 4–5). He bases his opinions on mechanical stress tests that he conducted on the Obtryx Transobturator Mid-Urethral Sling System ("the Obtryx") and Pinnacle products, his experience, scientific literature, and internal documents. (*See id.* at 3). BSC argues that Dr. Barker's opinions are unreliable and irrelevant. In particular, BSC argues that Dr. Barker's testing methodology was flawed, that his opinions are litigation driven, that he is unqualified to opine as to polypropylene and product design, and that Dr. Barker seeks to offer impermissible state of mind testimony.

I have previously reviewed the opinion testimony of Dr. Barker under *Daubert*. See *Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *5–10 (S.D. W. Va. Sept. 29, 2014). The parties in this case assert arguments on the admissibility of Dr. Barker’s expert opinion that I addressed in *Sanchez*. To the extent that there are differences in fact or exhibits, the court does not find them sufficiently material to this case. Thus, I **ADOPT** my prior ruling on Dr. Barker as follows and thereby **GRANT** BSC’s motion. I will address additional arguments raised by the parties in this case below.

1. Qualifications

BSC challenges Dr. Barker’s qualifications. In *Sanchez*, I found Dr. Barker qualified to opine as to the properties of polypropylene, and I **ADOPT** the same reasoning here:

Dr. Barker holds a Ph.D. in biomedical engineering and is currently on the faculty of a joint department within the Georgia Institute of Technology and Emory University School of Medicine. He states in his expert report that his research focuses on

the effects of mechanical forces and tissue/material mechanical properties (e.g. stiffness) on the host response. I am trained and have extensive expertise in the evaluation of biomaterial mechanical properties, biomaterial/implant design, the foreign body host response, and human tissues under repair and fibrosis, including analyses of cell/molecular biological outcomes.

([Barker Report [Docket 71-1],] at 2). He conducted postdoctoral research focusing on “exploring the mechanisms of biomaterial associated fibrosis (e.g. the foreign body response).” (*Id.*). Additionally, Dr. Barker has authored several book chapters and peer-reviewed articles on biomaterials and biomedical engineering. (*See id.*).

Sanchez, 2014 WL 4851989, at *5–6. As I note in *Sanchez*, even though Dr. Barker is qualified, I must still determine that his method is reliable. *Id.* at 6.

2. Admissibility of Opinions Based on Dr. Barker’s Mechanical Testing

BSC argues that Dr. Barker's opinions based on his mechanical testing are unreliable and irrelevant. In particular, BSC argues that Dr. Barker's testing is flawed because it "1) does not replicate the published protocol he claims to have followed; 2) fails to utilize a sufficient sample size; 3) fails to meet the standards required for publication in a peer-reviewed journal; and 4) does not replicate the physiological environment or forces experienced in the female pelvic floor." (Def. BSC's Mem. of Law in Supp. of Its Mot. to Exclude the Ops. and Test. of Thomas H. Barker, Ph.D. ("BSC's Mem. re: Barker") [Docket 91], at 5). In *Sanchez*, BSC raised the same arguments.

a. Dr. Barker Failed to Follow Published Protocols

BSC argues that Dr. Barker's failure to soak the pieces of mesh in a saline bath, contrary to published protocols, is unreliable. The Shepherd and Moalli protocols call for the use of a saline bath as part of testing to help better replicate the physiological environment of the human body. In *Sanchez*, I found that this deviation from protocols without a scientific basis rendered his method flawed:

His only reasoning was that Georgia Tech denied him permission to submerge its equipment in saline, a "potentially corrosive" solution. (*Id.* at 197:20–198:21). The difference in the results obtained by Dr. Barker and by Drs. Shepherd and Moalli further demonstrate the unreliability of his method. Dr. Barker's tests revealed two to four times more relative elongation of the mesh than Drs. Shepherd and Moalli's tests. (*See* Shepherd, *supra*, at 617; Moalli, *supra*, at 662; Barker Report [Docket 71-1], at 21).

Sanchez, 2014 WL 4851989, at *7. Moreover, I found that the use of a saline bath to replicate the human body was particularly important because Dr. Barker seeks to opine as to the in vivo effects of mesh. *See id.* For the reasons stated above and in *Sanchez*, I find Dr. Barker's methodology to be unreliable.

b. Dr. Barker Failed to Use a Sufficient Sample Size

BSC next argues that Dr. Barker failed to use a sufficient sample size when he tested one piece of Obtryx mesh and 2 pieces of Pinnacle mesh. In *Sanchez*, I agreed with this argument, especially since Dr. Barker admitted that a statistical test cannot be performed on a sample size of one:

Dr. Barker admits that having a sample size of one is “insufficient to perform statistical analysis.” (Dr. Barker Dep. [Docket 71-4], at 233:17–234:5). As a result, it is difficult to predict whether his results were merely chance occurrences. Dr. Barker explains that he wanted additional materials and he would have conducted additional testing if they had been provided:

Q: In fact, a lot of the results that Dr. Moalli has published that are different than your results, don’t you think you need to test another piece of Obtryx mesh to confirm or not confirm the results that you got based on your N equals 1?

A: I would have liked to have been provided with materials, additional materials to do additional testing.

(*Id.* at 233:3–12) (objections omitted). Dr. Barker similarly testified about his sample size of two for the Pinnacle:

Q: Now, with regard to the Pinnacle device, you had N equals 2, right?

A: That's correct.

Q: Okay. Did you do anything to determine the statistical confidence levels with regard to the testing that you performed on the two pieces of Pinnacle mesh?

A: You cannot likewise perform a statistical test on an N of 2. A minimum is a minimum of 3.

(*Id.* at 236:11–20). Dr. Barker’s testing of merely one or two samples lacks reliability.

Sanchez, 2014 WL 4851989, at *7–8. Dr. Barker’s sample size was a flaw in his method.

c. Dr. Barker's Testing Failed to Meet Peer Reviewed Standards

BSC argues that Dr. Barker's testing was flawed because it was not up to peer-reviewed standards. In *Sanchez*, I noted that Dr. Barker admits to this in his deposition testimony:

Q: Would you agree with me that your testing that you performed on the Obtryx with an N of 1 wouldn't meet standards to be published in a peer-reviewed journal?

A: I would.

Q: And would you agree with me that your testing that you did on Pinnacle with an N of 2 wouldn't meet the standards to be published in a peer reviewed journal?

A: I would agree.

Id. at *8 (citing Barker Dep. in *Sanchez* [Docket 71-4], at 301:20–302:5). I **ADOPT** this same reasoning here and find that this factor weighs against finding Dr. Barker's method reliable.

d. Dr. Barker's Testing Did Not Replicate In Vivo Conditions

BSC argues that Dr. Barker's method is flawed because it failed to replicate the physiological multi-directional forces in the female pelvic floor. In *Sanchez*, I agreed that Dr. Barker's uniaxial testing was unreliable to base opinions on the behavior of the mesh in vivo:

[B]ecause Dr. Barker's method did not account for the multi-directional forces inside of the female pelvis, his opinions about the effect of the mesh once implanted in vivo are unreliable and do not survive *Daubert* scrutiny. Even Drs. Shepherd and Moalli note that their studies do not conclusively reveal the mesh's behavior in the human body. (*See* Shepherd, *supra*, at 619 (stating that "this experimental setup allows us to draw only preliminary conclusions about the various meshes"); Moalli, *supra*, at 663 (noting that "the behavior of these slings in vivo and after incorporation into host tissue may be inferred, but is not directly apparent from these studies"))).

Sanchez, 2014 WL 4851989, at *9. I **ADOPT** this reasoning from *Sanchez* here, and based on the above four arguments I **FIND** Dr. Barker's method to be unreliable.

e. Plaintiffs Argue that Dr. Barker's Method Was Generally Accepted

In this case, the plaintiffs raise an additional argument as to the reliability of Dr. Barker's method. The plaintiffs contend that Dr. Barker's testing was generally accepted within the scientific community. (Pls.' Resp. in Opp'n to BSC's Mot. to Exclude the Opinions & Testimony of Thomas H. Barker, Ph.D. ("Pls.' Resp. re: Barker") [Docket 130], at 11–12). In support, the plaintiffs point to Dr. Barker's deposition testimony, where he explains that his general method of testing material—reading relevant scientific literature, developing a testing protocol, and then conducting “cyclic tensile testing and stress deformation analyses” in accordance with the developed testing protocol—is generally accepted within his field. (Barker Dep. [Docket 130-4], at 324:7–327:16). The plaintiffs argue that general acceptance “definitively forecloses a *Daubert* challenge.” (Pls.' Resp. re: Barker [Docket 130], at 12).

The trial judge must “ensur[e] that an expert's testimony . . . rests on a reliable foundation” and has “flexib[ility]” in making this assessment. *Daubert*, 509 U.S. at 594, 597. Even if cyclic tensile testing and stress deformation analyses are generally accepted in the bioengineering field, the plaintiffs' argument does not cure the fatal deficiency in Dr. Barker's method—that he failed to take measures to replicate the human body when forming and providing opinions as to the mesh's behavior in vivo. For the reasons stated above and in *Sanchez*, I find Dr. Barker's methodology to be unreliable. *See Sanchez*, 2014 WL 4851989, at *5–10.

Therefore, as I concluded in *Sanchez*, Dr. Barker's method was unreliable and his opinions based on this method are **EXCLUDED**.

3. Opinion Regarding the Mechanical Mismatch Between the Mesh and the Human Body

BSC challenges Dr. Barker's opinion regarding a mechanical mismatch between the mesh and the human body and the adverse in vivo effects resulting from that mismatch. BSC argues that it is unreliable. In *Sanchez*, I agreed because Dr. Barker based his calculation as to the mesh on his unreliable testing:

[H]e based his elastic modulus calculations of the Pinnacle mesh on his methodologically flawed and unreliable testing. . . Furthermore, as explained above, Dr. Barker's testing does not replicate the forces and environment of the human body and, therefore, his opinions regarding the mesh's effects in vivo are unreliable.

Id. at *9. I **ADOPT** this reasoning here and find that Dr. Barker's opinions based on the mechanical mismatch are unreliable and, thus, **EXCLUDED**.

4. BSC Argues that Dr. Barker's Opinions are Litigation Driven

BSC states that "Dr. Barker's opinions are unreliable because they are litigation driven[.]" (BSC's Mem. re: Barker [Docket 91], at 2). BSC raised this same argument in *Sanchez*, and, thus, I **ADOPT** my reasoning:

[O]therwise reliable expert testimony will be admitted even if litigation driven. Because I find Dr. Barker's opinions to be otherwise unreliable and inadmissible, I need not address this argument.

Sanchez, 2014 WL 4851989, at *9.

5. Relevancy of Dr. Barker's Opinions Based on His Testing of the Obtryx

Dr. Barker tested both the Pinnacle and Obtryx products. The Pinnacle is the product at issue in this case, but the Obtryx device is not at issue in this case. Because I find his opinions to be unreliable, I need not address the relevancy of Dr. Barker's opinions based on his testing of the Obtryx device. *See Daubert*, 509 U.S. at 594–95 (noting reliability and relevancy requirement for expert testimony).

6. Plaintiffs' Relevancy Argument Regarding *Lewis v. Ethicon, Inc.*

In this case, the plaintiffs raise an additional argument as to the relevancy of Dr. Barker's testimony. The plaintiffs argue that "[t]he crux of Dr. Barker's opinions, and hence his role in this case, is to provide expert evidence of the precise design engineering failure in BSC's meshes." (Pls.' Resp. re: Barker [Docket 130], at 16). As a result, the plaintiffs contend that "Dr. Barker's opinions provide the precise evidence that the plaintiff in *Lewis v. Ethicon, Inc.* lacked and warranted a directed verdict[.]" and that, therefore, his testimony is helpful to a jury. (*Id.* (citing *Lewis* trial transcript)).

As I explained in *Sanchez*, I find Dr. Barker's method to be unreliable, and I exclude his opinions on this basis. As a result, I do not need to address the relevancy of Dr. Barker's testimony. *See Daubert*, 509 U.S. at 594–95 (noting requirement that expert testimony be both reliable and relevant). However, I note that the portions of the *Lewis* trial transcript in which the plaintiffs cite in support of their argument refer to specific causation. (*See* Pls.' Ex. A *Lewis* Trial Tr. [Docket 130-1], at 60:5–22, 62:10–15). Dr. Barker does not offer specific causation opinions here.

7. Dr. Barker's Proposed State of Mind Testimony

BSC argues that Dr. Barker is unqualified to opine as to product design or testing and that his proposed state of mind testimony is inadmissible. In *Sanchez*, BSC made these same arguments. However, I did not reach the issue of Dr. Barker's qualifications as to product design or testing because I found his state of mind testimony to be impermissible expert testimony:

Dr. Barker contends that "BSC designed the Pinnacle . . . to meet the specification of substantial similarity to products pre-existing on the market, rather than engage in the engineering and design process of development of a safe and effective medical product (even for one similar to a pre-existing product in the market)"

and that this “is inconsistent with appropriate medical device design principles.” (Barker Report [Docket 71-1], at 4, 15). These opinions relate to the state of mind of BSC and are, thus, **EXCLUDED**.

Sanchez, 2014 WL 4851989, at *10. I **ADOPT** this reasoning from *Sanchez* in this case.

Therefore, I **GRANT** BSC’s Motion to Exclude the Opinions and Testimony of Thomas H. Barker, Ph.D. [Docket 90] on the grounds explained above and in *Sanchez*. *See id.* at *5–10.

D. Motion to Exclude the Testimony of Jimmy W. Mays, Ph.D. & Samuel P. Gido, Ph.D.

BSC seeks to exclude the opinions of Dr. Jimmy W. Mays and Dr. Samuel P. Gido. Dr. Mays is a Distinguished Professor of Chemistry at the University of Tennessee, and Dr. Gido is an Associate Professor of Polymer Science and Engineering at the University of Massachusetts Amherst. (Mays & Gido Report [Docket 93-1], at 2, 4). Both have worked extensively in the area of polymer materials. Drs. Mays and Gido issued a joint expert report examining and assessing the polypropylene material mesh BSC used in the Pinnacle product. (*Id.* at 5). In their report, Drs. Mays and Gido conclude that (1) polypropylene is susceptible to oxidation and degrades by an oxidative mechanism in the body; (2) analysis of explanted BSC Pinnacle mesh shows clear signs of oxidative degradation; and (3) the Pinnacle is thus defective and not suitable to serve as a permanent implant. (*Id.*). The report states that Drs. Mays and Gido relied upon their training and experience, provided materials, and underlying data from the testing in forming their opinions. (*Id.*). However, as discussed below, the deposition testimony proves otherwise. The reasoning in *Sanchez, et al. v. Boston Scientific Inc.*, No. 2:12-cv-05762, 2014 WL 4851989, at *24–30 (S.D. W. Va. Sept. 29, 2014), substantially reflects the court’s view of these issues as presented in this case. To the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. The *Sanchez* excerpts quoted throughout are to explicate the

conclusions the court reaches below.

BSC argues that Drs. Mays and Gido's testing and the clinical conclusions drawn from that testing must be excluded because their testing is unreliable and their opinions are irrelevant. (BSC's Mem. of Law in Supp. of its Mot. to Exclude the Ops. & Test. of Jimmy W. Mays, Ph.D. & Samuel P. Gido, Ph.D ("BSC's Mem. re: Mays & Gido") [Docket 93], at 2). Additionally, BSC argues that Drs. Mays and Gido's opinions are unreliable because they are litigation driven, as well as a poor fit that would not be helpful to the jury. (*Id.*). Finally, the defendant argues that some of the opinions offered by Drs. Mays and Gido should be excluded because they opine about BSC's state of mind and make inadmissible legal conclusions. (*Id.*).

1. Chemical & Microscopic Testing

a. Background

As BSC takes particular issue with Drs. Mays and Gido's testing of the Pinnacle explants, I will briefly discuss their testing procedures and results. Drs. Mays and Gido received exemplars of Pinnacle and Obtryx products on September 24, 2013. (Mays & Gido Report [Docket 93-1], at 24). These exemplars were used as a control. (*Id.* at 18). The plaintiffs' counsel, Ms. Jennifer Black, arranged for Drs. Mays and Gido to also receive Pinnacle and Obtryx mesh explants from Steelgate, a repository for explanted transvaginal mesh. (Aff. of Jennifer Black [Docket 134-5], ¶¶ 5–6, 12). Ms. Black identified the available BSC Pinnacle and Obtryx explants by cross-referencing the firm's client list with the patient list retained by Steelgate. (*Id.* ¶¶ 9–11). Ms. Black determined that there were a total of fourteen such explants at Steelgate. (*Id.* ¶ 8). After identifying these explants, Ms. Black requested that the explants be sent to Dr. Gido with the appropriate chain of custody. (*Id.* ¶ 12).

On October 1, 2013, Dr. Guido received the fourteen explants. (Mays & Guido Report [Docket 93-1], at 24). The explants were sealed in plastic containers and came with chain of custody documentation. (*Id.*). Only eleven of the fourteen explants contained mesh suitable for testing. (*Id.*). Dr. Guido proceeded to conduct three microscopic analyses of the eleven explants: (1) Scanning Electron Microscopy (“SEM”) to take pictures of the mesh fibers at high magnification and compare those images to the images published in the literature; (2) Energy Dispersive Spectroscopy (“EDS”) to determine if there was oxygen in the mesh fibers; and (3) Transmission Electron Microscopy (“TEM”) to identify amorphous regions in the mesh fibers that are more susceptible to oxidation. (*Id.* at 18).

Utilizing Steelgate’s chain of custody, Dr. Guido sent the samples to Dr. Mays on October 22, 2013. (*Id.*). Only four of the samples sent by Dr. Guido had sufficient amounts of polypropylene mesh adequate for testing by Dr. Mays. Dr. Mays conducted three chemical analyses of the four samples: (1) Fourier Transform Infrared Spectroscopy (“FTIR”), a testing instrument that uses infrared to identify chemical groups containing oxygen; (2) Gel Permeation Chromatography (“GPC”), a test that separates molecules by size and quantifies the molecular weight of the polymer, which allowed Dr. Mays to estimate the reduction in molecular weight of the polypropylene explants; and (3) Thermogravimetric Analysis (“TGA”) to determine if there were other additives or inorganic materials in the mesh. (Mays Dep. [Docket 93-2], at 49–50).

Drs. Mays and Guido included the following summary of results in their expert report:

SAMPLE	LENGTH OF TIME IMPLANTED	IMPLANT TIME CLASSIFICATION	MODEL	Cracking Observed by SEM	Oxidation In Fibers Observed by EDS	Oxidation In Fibers Observed by FTIR	Mz from GPC	Mw from GPC	Mw/Mn from GPC
Obtryx Control	—	None		0	no	no	1,030,000	377,000	4.26
Pinnacle Control 1	—	None		0	trace amounts	no	1,151,000	388,000	5.97
Pinnacle Control 2	—	None		0	no*	not tested			
XP-1	1 YR, 4 MOS.	Short	Obtryx Halo	2	yes	not tested			
XP-2	1 YR, 6.5 MOS.	Short	Pinnacle	0	yes	not tested			
XP-3	1 YR, 7 MOS.	Short	pinnacle	0	yes	yes	648,000	291,000	3.44
XP-4	1 YR, 10 MOS.	Short	Pinnacle	3	yes	not tested			
XP-5	2 YRS, 2.5 MOS.	Intermediate	Pinnacle	1	yes	not tested			
XP-6	2 YRS, 11 MOS.	Intermediate	Pinnacle	0	yes	not tested			
XP-7	3 YRS, 3 MOS.	Intermediate	Pinnacle	4	yes	yes	847,000	344,000	3.95
XP-8	4 YRS, 1 MO.	Long	Pinnacle	5	not tested	yes	735,000	326,000	3.53
XP-9	4 YRS, 4 MOS.	Long	Pinnacle	4	yes	not tested			
XP-10	4 YRS, 5 MOS.	Long	Pinnacle	3	yes	yes	742,000	314,000	3.91
XP-11	4 YRS, 9 MOS.	Long	Obtryx Halo	5	yes	not tested			

(Mays & Gido Report [Docket 93-1], at 19). However, Dr. Mays did not include the protocol or results of the TGA or TEM in the expert report. Instead, for the TGA, he produced that information to BSC in the form of his handwritten notes, which were taken from his lab notebook. (Mays Dep. [Docket 93-2], at 49–50).

b. Reliability

With respect to the reliability of Drs. Mays and Gido's testing, BSC makes several specific arguments. However, I have previously reviewed the reliability of Drs. Mays and Gido's testing under *Daubert* and found their opinions unreliable because they (1) failed to control for error or bias and (2) did not establish or adhere to testing protocols. *See Sanchez*, 2014 WL 4851989, at *26. In *Sanchez*, I made the following findings:

i. Lack of Control for Error or Bias

Although plaintiffs' counsel selected the samples, counsel explained that these were the only Pinnacle and Obtryx samples available in the Steelgate repository. Therefore, unlike *Lewis v. Ethicon, Inc.*, where Dr. Klinge did not indicate whether the meshes examined constituted a large sample size of the repository's collection, here, these were the only samples available for testing. Furthermore, certain samples were not tested because they did not have enough mesh, not because of bias. Despite the differences in these two cases, the fact that Drs. Mays and Gido's sample was not very large or randomly selected affects the reliability of their testing. *See Edwards v. Ethicon*, No. 2:12-cv-09972, 2014 WL 3361923,

at *39 (S.D. W. Va. July 8, 2014) (excluding plaintiffs' expert's analysis of pelvic mesh explants generally). Drs. Mays and Gido "[have] given no explanation as to whether [theirs] is a representative sample size Therefore I have no information as to the potential rate of error inherent in [their] observations." *Lewis*, 2014 WL 186872, at *8. Additionally, Drs. Mays and Gido have no knowledge of how the material they examined was explanted or how it was preserved and handled before reaching their lab. (Mays Dep. [Docket 99-1], at 304–05).

Dr. Gido conducted EDS testing to differentiate between polypropylene fibers and biological material. In their report, Drs. Mays and Gido state that "the presence or absence (or near absence) of nitrogen as detected by EDS is the key discriminator between clean polypropylene fibers from which valid conclusions can be drawn or biomaterial covered fiber from which conclusions are less straightforward." (Mays & Gido Report [Docket 98-1], at 31). At his deposition, Dr. Gido acknowledged that on a relatively clean sample "there might be a little blip of nitrogen [in the EDS] and the question is, you know, is that nitrogen statistically significant." (Gido Dep. [Docket 99-2], at 154). However, Dr. Gido never determined the significance of potential "blips," although the data was available. (*Id.* ("I did not do that analysis, although the data is all there, and if that analysis needs to be done, I would contend it is not a new opinion."))).

Similarly, in their report, Drs. Mays and Gido state that "[w]e need to base our conclusions related to fiber degradation on clean polypropylene fibers and make sure we are not looking at biological films coating the fibers." (Mays & Gido Report [Docket 98-1], at 31). However, both Dr. Mays and Dr. Gido admit in their depositions that their inconsistent bleach treating techniques may have failed to remove all biologic material from the test samples. (*See* Mays Dep. [Docket 99-1], at 208; *see also* Gido Dep. [Docket 99-2], at 165). When asked explicitly whether they completed a statistical analysis or calculated a rate of error based on their tests, Dr. Gido admitted they did not. (Gido Dep. [Docket 99-2], at 154–55).

The key *Daubert* inquiry is "whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions." *Daubert II*, 43 F.3d at 1317. The small sample size and Drs. Mays and Gido's failure to determine the statistical significance of their results call into the question the reliability of their methods. Although *Daubert* is a flexible inquiry, these facts weigh heavily against the reliability of their opinions.

ii. Failure to Establish or Adhere to Testing Protocol

First and most simply, Dr. Mays states that "SEM is a very common tool," but when asked if he prepared any written methodology before completing the SEM

testing, he admits that he did not. (Mays Dep. [Docket 99-1], at 162). In addition, Dr. Mays and Dr. Gido both reference Dr. Gido's completely subjective cracking standard he came up with for purposes of their testing. Dr. Mays admits that the standard cannot be found in any published material, and Dr. Gido admits that he has never created or used a cracking standard before. (*See id.* at 18; *see also* Gido Dep. [Docket 99-2], at 161).

Expanding on the brief discussion above, while the samples were with Dr. Gido for testing, Dr. Mays asked Dr. Gido to try bleach cleaning one of the explants to see if it was effective. (Gido Dep. [Docket 99-2], at 167). Dr. Gido used a 6% bleach concentration on explanted sample 11. (*See id.* at 193; Mays & Gido Addendum Report [Docket 111-5], at 2). In comparison, Dr. Mays used a 7.8% concentration to clean the explants and controls before testing. (*See* Mays & Gido Report [Docket 98-1], at 33). The bleach treatments were clearly inconsistent. Additionally, Drs. Mays and Gido have no explanation as to why a discussion of this testing was "mistakenly" omitted from their original report. (Mays Dep. [Docket 99-1], at 202).

Another mistake occurred after Dr. Gido returned the samples, and he discovered that he failed to conduct an EDS test on one of them, which he attributed to a mere oversight. (Gido Dep. [99-2], at 214–15). Finally, Dr. Mays conducted TGA testing on the explants to determine what additives were in the mesh, but for some reason did not include the results in their expert report. (*Compare* Mays Dep. [Docket 99-1], at 50, *with* Mays & Gido Report [Docket 98-1]).

Although Drs. Mays and Gido performed tests that are supported by the literature, the haphazard application of these tests, errors, and changes to their report lead to the conclusion that their methodology is unreliable. Vigorous adherence to protocols and controls are the hallmarks of "good science." *See Black v. Rhone-Poulenc, Inc.*, 19 F. Supp. 2d 592, 603 (S.D. W. Va. 1998). Accordingly, I **FIND** that the testing performed by Drs. Mays and Gido is unreliable, and therefore, **EXCLUDED**.

Sanchez, 2014 WL 4851989, at *26–28. The parties in this case assert the same arguments regarding the reliability of Drs. Mays and Gido's testing that I addressed in *Sanchez*, and I **ADOPT** my prior ruling on the reliability of Drs. Mays and Gido's testing.

2. Expert Opinions Not Based on Testing⁵

⁵ I previously allowed a joint expert report, *see In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 644 (S.D. W. Va. 2013) (discussing the "Exponent Experts"), and there is "no reason to think the practice [is] always and inherently impermissible" under Rule 26. *Dale K. Barker Co., P.C. v. Valley Plaza*, 541 F. App'x 810, 815 (10th Cir. 2013)

a. Background

While BSC argues that Drs. Mays and Gido's unreliable testing should be excluded entirely, the plaintiffs respond by explaining that the testing "merely confirmed what [Drs. Mays and Gido] have long known because of their training, experience, and peer-reviewed published scientific literature." (Pls.' Mem. in Opp'n to BSC's Mot. to Exclude Test. of Pls.' Expert ("Pls.' Mem. re: Mays & Gido") [Docket 134], at 4).⁶ The plaintiffs contend that both the expert report and depositions support this explanation; however, they conveniently choose to cite only Dr. Mays's deposition in support of their proposition. (*See id.* at 4–5; *see also* Mays Dep. [Docket 134-3], at 65 ("I believe all of my conclusions are ones that one could reach simply by looking at published literature on polypropylene that's been implanted into the human body combined with the knowledge of chemistry and polymer science and the behavior of polymeric materials."); *id.* at 140 ("So my opinion is based on my experience as a scientist, as a chemist. It's based on all the literature we looked at. It's based also on the testing that we did in this report."); *id.* at 260 ("My opinion in this case, and it was my opinion before I got involved in this case, is that polypropylene is so fundamentally susceptible to oxidative degradation that it's a poor choice for permanent implant where there's going to be tissue ingrowth.")).

The plaintiffs fail to point out or cite Dr. Gido's deposition testimony, which takes the opposite position. Dr. Gido explicitly states that "we're making this statement based on our own

(explaining that "[c]o-authored expert reports aren't exactly uncommon"). For example, in *Barker*, the Tenth Circuit allowed a joint report when both experts "reviewed the same materials, and, working together, came to the same opinions." *Id.* at 816. However, when a joint report is not built on a reliable foundation, and instead, is confusing and contradictory, it becomes problematic and potentially inadmissible. *See id.* ("[I]f, for example, it isn't clear whether both experts adhere to all of the opinions in the report and they do not delineate which opinions belong to which expert." (citing *Dan v. United States*, No. CIV 01-25 MCA/LFG-ACE, 2012 WL 34371519, at * 2–3, *5 (D.N.M. Feb. 6, 2002))).

⁶ Plaintiffs also argue that in addition to Drs. Mays and Gido's reliance on other sources, their testing is reliable, which is the same argument I considered and rejected above.

study and our own results. We're not getting it from the literature.” (Gido Dep. [Docket 134-2], at 233). While Dr. Mays describes the testing as “confirmatory,” Dr. Gido highlights the fact that he completed the testing first and then “got into the literature.” (Mays Dep. [Docket 134-3], at 65; Gido Dep. [Docket 134-2], at 50). Dr. Gido admits that he had not reached his opinions before testing and emphasizes how important the data was in drafting his portions of the report. (See Gido Dep. [Docket 134-2], at 51 (“I would suspect the same – you know, I would probably conclude that there would likely be a problem with polypropylene, but I would not be as sure of it as I am having seen data that I took with my own hands and seen Dr. Mays’s data.”)). Based on the depositions, Drs. Mays and Gido clearly have different opinions regarding the nature and influence of the testing they performed.

I have determined that Drs. Mays and Gido’s testing was unreliable, and Dr. Gido states that his opinions are based solely on the testing. Accordingly, I **FIND** that Dr. Gido’s opinions are **EXCLUDED**. However, as discussed more fully below, because Dr. Mays indicates that he relied primarily on other scientific sources, I **FIND** that Dr. Mays is permitted to testify generally about polypropylene degradation based on his experience and review of the literature.

b. Reliability

BSC argues that Dr. Mays’s opinions are not reliable because they are litigation driven, not scientific, and not fair and balanced. With respect to the argument that Dr. Mays’s expert testimony is litigation driven, I refer back to my above ruling that an expert’s formulation of his opinion for the purposes of litigation does not, by itself, justify that expert’s exclusion. As I **FIND** Dr. Mays’s opinions otherwise reliable, I need not address this argument further.

Next, BSC contends that Dr. Mays “selectively cite[s] several articles” and “fail[s] to

include contrary statements or literature in [his] report.” (BSC’s Mem. re: Mays & Gido [Docket 93], at 14). I have previously reviewed the reliability of Dr. Mays’s opinions under *Daubert*. See *Sanchez*, 2014 WL 4851989, at *29. The parties in this case assert the same arguments regarding the reliability of Dr. Mays’s expert opinions that I addressed in *Sanchez*. In *Sanchez*, I ruled as follows:

Dr. Mays cites eight different studies supporting his proposition that polypropylene is not suitable as a permanent implant, many of which are the same peer-reviewed, published literature relied upon by other experts in previous MDL trials. See *Lewis*, 2014 WL 186872, at *11 (discussing plaintiffs’ expert Dr. Uwe Klinge). Clearly these are studies reasonably relied upon in the field of polymer science. Additionally, Appendix C of the report lists 68 scholarly articles Dr. Mays considered in making his opinions, as well as hundreds of other documents. (Mays & Gido Expert Report App. C [Docket 111-3], at 1–22). If [BSC] take[s] issue with Dr. Mays’s failure to review or cite particular documents, this goes to the weight of his opinion, not its admissibility, and can be addressed on cross-examination.

Sanchez, 2014 WL 4851989, at *51.

Finally, BSC argues that Dr. Mays’s opinions are a poor fit and would not be helpful to a jury because Dr. Mays was not able to correlate degradation to any clinical symptoms in an individual patient. However, as I stated in *Sanchez*,

I have repeatedly held that general causation testimony, including degradation opinions, is admissible under Rule 702, even if the plaintiffs might fail to carry their burden as to specific causation. See, e.g., *Huskey*, 2014 WL 3362264, at *13. Additionally, in his deposition, Dr. Mays references complications that can arise in patients as a result of degradation. (Mays Dep. [Docket 99-1], at 131 (“I’m saying that degradation is the root cause of these devices failing to function the way they are designed in some cases and then the device not functioning properly is part of the problem.”)). To the extent that BSC believes degradation is not clinically significant, it may cross examine Dr. Mays on that issue.

Dr. Mays explicitly states that he relied not only on his knowledge and experience, but also on scientific literature, which are sufficiently reliable methods of forming his particular opinion. Accordingly, I **FIND** that Dr. Mays is permitted to testify generally that polypropylene is susceptible to oxidation and

degrades, without specifically referencing the unreliable testing he conducted with Dr. Gido.

Sanchez, 2014 WL 4851989, at *51–52. Therefore, I **ADOPT** my prior ruling on Dr. Mays, as stated in *Sanchez*, and **FIND** that his opinions based on his experience and review of scientific literature should not be excluded.

3. State of Mind

Dr. Mays offers two opinions regarding BSC’s state of mind and its knowledge of risks associated with polypropylene. (*See* Mays & Gido Report [Docket 93-1], at 5 (“BSC did not take into account polypropylene’s propensity for oxidation during design of its Pinnacle and Obtryx mesh.”); *id.* at 17 (“If the developers of Pinnacle and Obtryx were ignorant of this information on implantation of PP materials then they were incompetent to be in their line of business. If they were aware of these facts and chose to proceed anyway, they were taking an unconscionable, calculated gamble with the lives and wellbeing of others for the sake of their own profits.”)). As I previously discussed, expert opinions on BSC’s knowledge or state of mind are not helpful to the jury. *See* Fed. R. Evid. 702. Therefore, these opinions are **EXCLUDED**.

4. Legal Opinions

Dr. Mays offers two opinions that draw legal conclusions from the facts. (*See* Mays & Gido Report [Docket 93-1], at 17; *id.* at 19 (“The results of our own testing completely support and greatly strengthen this opinion that choice of PP as the material for the explants we tested rendered them unacceptably susceptible to degradation and was thus *incompetent and or negligent*.”) (emphasis added)). In the Fourth Circuit, “opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.” *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). Whether BSC failed to act as a

reasonable and prudent medical device manufacturer is a question for the jury. To be clear, Dr. Mays may offer opinions that, as a polymer scientist, he does not believe the Pinnacle is suitable to serve as a permanent implant, but his opinions cannot be phrased as legal conclusions. Therefore, these statements are **EXCLUDED**.

In conclusion, BSC's Motion to Exclude the Opinions of Drs. Mays and Guido [Docket 92] is **GRANTED IN PART** and **DENIED IN PART**.

E. Motion to Exclude the Opinions & Testimony of Emery Salom, M.D., FACOG

Dr. Salom, a licensed urogynecologist in Florida, began treating Plaintiff Dotres in 2008 when she complained of uterine and bladder prolapse. Dr. Salom treated her condition with the Pinnacle mesh implant. Plaintiff Dotres offers Dr. Salom to testify about his examination of Ms. Dotres, his treatment of Ms. Dotres's condition with the Pinnacle mesh system, Ms. Dotres's post-surgery complications, and his opinion regarding the cause of Ms. Dotres's post-surgery pelvic pain and dyspareunia.

BSC asserts two challenges to Dr. Salom's opinion testimony. First, BSC argues that the plaintiff failed to submit a proper expert report under Federal Rule of Civil Procedure 26(a)(2), and so the court must limit Dr. Salom's testimony to opinions based solely on his care and treatment of Ms. Dotres. Second, BSC maintains that even if the court excuses the improper expert report, Dr. Salom's testimony must nevertheless be limited in accordance with *Daubert*'s reliability and relevancy requirements. For the reasons discussed below, BSC's motion is **DENIED**.

1. Federal Rule of Civil Procedure 26(a)(2)(B)

Under Rule 26, "a party must disclose to the other parties the identity of any witness it

may use at trial.” Fed. R. Civ. P. 26(a)(2)(A). Furthermore, “if the witness is one retained or specially employed to provide expert testimony,” a party must accompany this disclosure with a written report detailing “a complete statement of all opinions the witness will express and the basis and reasons for them.” Fed. R. Civ. P. 26(a)(2)(B). Failure to provide this information results in exclusion of the witness at trial “unless the failure was substantially justified or is harmless.” Fed. R. Civ. P. 37(c). Regarding the testimony of treating physicians, Local Rule 26.1 provides that the disclosures required under Rule 26(a)(2)(B) “shall not be required of physicians and other medical providers who examined or treated a party . . . unless the examination was for the sole purpose of providing expert testimony in the case.” L.R. Civ. P. 26.1. When a Rule 26(a)(2)(B) disclosure is not required, as is usually the case for treating physicians, parties must supply a less stringent disclosure under Rule 26(a)(2)(C), stating the subject matter of the testimony and providing a summary of the witness’s opinion testimony. Fed. R. Civ. P. 26(a)(2)(C); *see also* Fed. R. Civ. P. 26 advisory committee’s note (explaining that Rule 26(a)(2)(C) frequently applies to “physicians or other health care professionals . . . who do not regularly provide expert testimony”).

In accordance with these rules, Plaintiff Dotres submitted a Rule 26 Expert Report for Dr. Salom (“the Report”). [Docket 95-1]. BSC asserts that the Report constitutes a Rule 26(a)(2)(C) disclosure rather than the required Rule 26(a)(2)(B) disclosure. Although the former type of report would be appropriate if Dr. Salom’s testimony focused solely on his treatment of Ms. Dotres, BSC argues that Dr. Salom’s offered opinion addresses information outside the scope of his treatment of Ms. Dotres such that the plaintiff should have submitted a full Rule 26(a)(2)(B) report. Because the Report does not comply with Rule 26, BSC asks this court to exclude all

testimony that goes beyond his treatment of Ms. Dotres. Specifically, Dr. Salom should be precluded from testifying that (1) “there is little long term data to show that the benefits of mesh augmented procedures outweigh the risks associated with mesh related procedures compared to native tissue repairs”; and (2) “the sacrospinous ligament fixation as directed by the Boston Scientific Pinnacle Kit can cause nerve damage that may result in pain in the S2–S4 nerve distribution.” (BSC’s Mem. in Supp. of Mot. to Exclude the Ops. And Test. of Dr. Emery Salom [Docket 95] (“BSC’s Mem. re: Salom”), at 5).

In response, the plaintiff has agreed to omit these two disputed opinions from her questioning of Dr. Salom. (*See* Pl.’s Resp. in Opp’n to BSC’s Mot. to Exclude the Ops. And Test. of Dr. Emery Salom [Docket 127] (“Pl.’s Resp. re: Salom”), at 6). Additionally, the plaintiff has assured the court that she will limit Dr. Salom’s opinion testimony to the causation of injuries sustained by his patient, Ms. Dotres, as required by *In re C. R. Bard, Inc.* (*Id.* at 5 (citing *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 616–17 (S.D. W. Va. 2013))). In reliance on these assurances, I **DENY** BSC’s motion on Rule 26 grounds.⁷

2. *Daubert* Challenges to Dr. Salom’s Testimony

I now turn to BSC’s *Daubert* challenges to Dr. Salom’s testimony. First, BSC seeks to exclude Dr. Salom’s opinion on the alleged risks of implanting the Pinnacle without properly cutting it. BSC asserts that Dr. Salom’s testimony about what might have happened had he conducted the implantation surgery differently fails the relevancy prong of *Daubert* because it

⁷ The plaintiff also attempts to argue that because BSC has not filed a Rule 26 report to disclose Dr. Salom as an expert, BSC should be “prohibited from seeking any opinion testimony on any subject from Dr. Salom.” (Pl.’s Resp. re: Salom [Docket 127], at 3). Rule 26 only applies to the party offering the witness as an expert. *See* Fed. R. Civ. P. 26 (a)(2)(A) (“A party must disclose to the other parties the identity of any witness *it may use* at trial to present [expert] evidence.”) (emphasis added). Plaintiff Dotres offers Dr. Salom as an expert witness, and only she has the obligation to disclose him as an expert under Rule 26. BSC is free to cross examine Dr. Salom’s opinions without having to file a Rule 26 report. If, however, BSC seeks to call Dr. Salom as an expert witness for the defense, then BSC must file a proper Rule 26 report.

does not relate to what actually happened in Ms. Dotres's case. Plaintiff Dotres has agreed to not elicit any opinions from Dr. Salom related to the risks of implanting the Pinnacle without cutting it properly. (*See* Pl.'s Resp. re: Salom [Docket 127], at 6). As such, I **DENY** BSC's argument under *Daubert* with respect to this opinion.

Second, BSC seeks to exclude Dr. Salom's testimony about Ms. Dotres's current condition, even though Dr. Salom has not treated Ms. Dotres since March 2012. BSC contends that Dr. Salom's opinions on Ms. Dotres's current medical condition constitute "nothing more than inadmissible hypothetical speculation and should be excluded." (BSC's Mem. re: Salom [Docket 95], at 9). Plaintiff Dotres has agreed not to elicit opinions from Dr. Salom about Ms. Dotres's condition since the last time he treated her in March 2012. (*See* Pl.'s Resp. re: Salom [Docket 127], at 6). Therefore, I **DENY** BSC's argument under *Daubert* regarding Dr. Salom's testimony to this effect.

I quickly address the plaintiff's primary response to BSC's motion to exclude, which is that if the plaintiff is "limited or precluded from eliciting testimony that is not derived exclusively from Dr. Salom's care and treatment of Ms. Dotres, then Boston Scientific must obviously also be so limited." (*Id.* at 3). BSC will of course be bound by the Federal Rules of Evidence in its questioning of Dr. Salom at trial. First, BSC's cross-examination of Dr. Salom will be limited by the scope of the plaintiff's direct examination. *See* Fed. R. Evid. 611 ("Cross-examination should not go beyond the subject matter of the direct examination and matters affecting the witness's credibility."). In the event that BSC's cross-examination violates Rule 611, the plaintiff may object at trial. Second, if BSC calls Dr. Salom as a fact witness, it must demonstrate that Dr. Salom has "personal knowledge" of the subject matter. Fed. R. Evid.

602(a). If the plaintiff wishes to challenge Dr. Salom's personal knowledge of proffered factual testimony, she may raise the objection at trial. And under Rule 26, BSC may not call Dr. Salom as an expert witness for the defense at trial because BSC has not filed a Rule 26 disclosure. In sum, the substance of a cross-examination leaves a great deal to the court's discretion, and questions asked during a deposition do not necessarily reflect what will develop at trial. Therefore, this *Daubert* ruling is not the proper forum for the concerns raised in the plaintiff's response, and the plaintiff should object at trial if warranted.

For the reasons set forth above, BSC's Motion to Exclude the Opinions and Testimony of Dr. Salom [Docket 94] is **DENIED**.

F. Motion to Exclude the Testimony of Dr. Peggy Pence, Ph.D.

Dr. Pence works as a clinical and regulatory consultant, providing "advice, guidance, and product development services to pharmaceutical/biopharmaceutical and medical device companies in the areas of strategic planning, preclinical testing, clinical trials, design and conduct, and regulatory matters involving the [FDA]." (Pence Report [Docket 97-1], at 1). During her career, she has accumulated knowledge about and experience with the testing requirements for medical devices; the development and content of product labeling; and the procedures necessary to comply with regulatory and industry standards, including those set forth by the FDA. (*See id.* at 1–4). In this matter, Dr. Pence offers four opinions: (1) BSC did not conduct adequate testing of the Pinnacle product prior to placing them on the market; (2) the Pinnacle product was inadequately labeled; (3) patients could not adequately consent to the surgical implantation of the Pinnacle due to the misbranding of these products; and (4) BSC

failed to meet the post-market vigilance standard of care for their products, leading to further misbranding. BSC seeks to exclude Dr. Pence's testimony in its entirety.

I have previously reviewed the opinion testimony of Dr. Pence under *Daubert*. See *Sanchez et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *32–36 (S.D. W. Va. Sept. 29, 2014). The reasoning in *Sanchez* substantially reflects the court's view of this issue as presented here. To the extent that there are differences in fact and exhibits, the court does not find them sufficiently material as to the ruling on Dr. Pence. Therefore, I **ADOPT** my prior ruling on Dr. Pence as follows and thereby **GRANT IN PART** and **DENY IN PART** her expert opinion.

1. Dr. Pence's Qualifications

I first address BSC's argument that this court should exclude Dr. Pence's opinions because she lacks the qualifications necessary to make them. BSC maintains that Dr. Pence's work as a researcher and consultant does not qualify her to opine about the safety and efficacy of mesh products, as she attempts to do in her expert report. In BSC's view, without a medical degree and without experience in the development of polypropylene mesh, Dr. Pence's opinions on BSC's medical devices cannot withstand *Daubert*.

In *Sanchez*, I ruled as follows, and I **ADOPT** that ruling here:

The absence of a medical degree on Dr. Pence's curriculum vitae does not call into doubt Dr. Pence's demonstrated knowledge about and experience with medical devices like the Pinnacle. Dr. Pence has over forty years of experience in the research and development of medical devices. (Pence Report [Docket 118-1], at 1). Over that time, she has accumulated knowledge that is relevant to this case, such as the design of clinical trials for diseases of the female genital system, the clinical testing of novel medical devices, and the content of product labeling. Accordingly, . . . I **FIND** that Dr. Pence is qualified to render the opinions set forth in her expert report, including her opinions about the safety and efficacy of mesh products and the sufficiency of BSC's product branding.

Sanchez, 2014 WL 4851989, at *33.

2. Dr. Pence's Opinions on Appropriate Pre-Market Testing

Having found that Dr. Pence is qualified to offer these opinions, I next address whether her opinions are relevant and reliable. In her report, Dr. Pence opines:

BSC should have performed adequate preclinical and clinical testing of the Obtryx Sling and Pinnacle PFR Kits prior to marketing to ensure the devices were reasonably safe for permanent implantation. By its failure to do so, BSC fell below the standard of care required of a reasonably prudent medical device manufacturer.

(Pence Report [Docket 97-1], at 44). In reaching this conclusion, Dr. Pence considered the risks associated with polypropylene mesh (*id.* at 31–36); the statements in Material Safety Data Sheets provided by the polypropylene supplier in 2004 indicating that polypropylene should not be used for permanent implantation in the human body (*id.* at 36–40); and the developmental history of BSC products (*id.* at 41–43).

In *Lewis, et al. v. Ethicon*, Dr. Pence gave a similar opinion. No. 2:12-cv-4301, 2014 WL 186872, at *18–19 (S.D. W. Va. Jan. 15, 2014). She opined that the defendant did not conduct the required investigative tests on the specific risks of a transvaginal mesh product, but she failed to support this opinion with any authority suggesting that the performance of such tests was needed. *Id.* at 18. Without a reliable foundation, I excluded Dr. Pence's opinion as unreliable. *Id.* at 19. Here, BSC argues that Dr. Pence's expert report should again be excluded as unreliable because it fails to point to any authority requiring BSC to perform the tests that Dr. Pence believes should have been conducted. The plaintiffs counter that Dr. Pence has revised her report to fix the deficiencies identified in *Lewis*. This time around, the plaintiffs argue, Dr. Pence has “clearly demonstrated that her methodology and opinions were not based upon her ‘professional

opinion’ alone” and instead arose from her review of a “voluminous amount of peer-reviewed scientific articles, data, government codes and regulation, deposition testimony provided in this litigation, and internal documents received from BSC.” (Pls.’ Resp. in Opp’n To BSC’s Mot. to Exclude Dr. Peggy Pence [Docket 142], at 5).

In *Sanchez*, I agreed with the plaintiffs and concluded that

Dr. Pence’s bolstered expert report [Docket 118-1] has tempered my previous concerns about the reliability of her opinion on this issue. Dr. Pence has cited to multiple sources that stress the importance of running clinical trials before incorporating mesh materials into a surgical product. For instance, she describes a 2006 study conducted by the French National Authority for Health (“HAS”), in which it evaluated the safety and efficacy of vaginally implanted mesh for the treatment of genital prolapse. (Pence Report [Docket 118-1], at 9). HAS concluded that “the use of mesh implants for transvaginal correction of genital prolapse remained a matter of clinical research” and recommended prospective studies on the anatomical and functional outcomes of mesh implantation, the mid-to long-term effects, possible adverse events like erosion, and the management of erosions and retractions. (*Id.* at 10). Dr. Pence also discusses the recommendations of the National Institute for Health and Care Excellence, which include the warning that transvaginal mesh repair “should be used with special arrangements for clinical governance, consent and audit or research.” (*Id.* at 43).

In contrast with *Lewis*, Dr. Pence’s opinion in this case is backed by authoritative studies that recommend the performance of clinical trials and long-term follow-ups before using polypropylene mesh. Thus, her opinion on the inadequacy of BSC’s pre-market testing is more than a bare declaration of her professional opinion. Accordingly, I **FIND** that Dr. Pence’s methodology is reliable under *Daubert* and **DENY** BSC’s motion with respect to this opinion.

Sanchez, 2014 WL 4851989, at *34. I **ADOPT** this ruling here.

3. Dr. Pence’s Opinions on the Adequacy of BSC’s Product Labels

Dr. Pence proffers two opinions regarding the labeling of the Pinnacle. First, she states that “BSC marketed [these products] without adequate instructions for use throughout the life of these products . . . , in particular, without adequate warnings, precautions, and information about the likelihood and extent of potential risks.” (Pence Report [Docket 97-1], at 62). Second, she

states that “patients implanted with the Obtryx Sling or Pinnacle mesh were prevented from . . . giving true informed consent as a result of BSC’s inadequate professional and patient labeling.” (*Id.* at 63). She then offers a list of warnings and risks that she believes should have been included in the products’ instructions for use (“IFU”) and patient brochures.

BSC asserts that these opinions should be excluded because they relate to BSC’s deviation from the branding requirements of the Food, Drug, and Cosmetic Act (“FDCA”), which is irrelevant in this case and consequently unhelpful to the jury. The plaintiffs agree that whether BSC violated the FDCA is not relevant and that Dr. Pence will not offer an opinion on that issue. The plaintiffs stress, however, that Dr. Pence’s testimony about labeling is relevant to the plaintiffs’ failure to warn claim. To assess the validity of this claim, the jury will need to understand what information should be included in IFUs and patient brochures but was not included by BSC—the plaintiffs argue that Dr. Pence can provide such understanding to the jury. I agree that such testimony might help guide the jury in reaching a verdict on these state law claims, which consider the appropriateness of product labeling, and as such, her opinions are relevant.⁸ *See, e.g., Church v. Wesson*, 385 S.E.2d 393, 396 (W. Va. 1989) (explaining that in failure to warn cases, “the focus is not so much on a flawed or physical condition of the product, as on its unsafeness arising out of failure to adequately label, instruct or warn” (quoting *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 682 (W. Va. 1979))).

BSC adds that even if Dr. Pence’s opinions on BSC’s labeling practices are relevant, they lack a reliable basis. In BSC’s view, Dr. Pence does not provide any authority supporting her

⁸ In *Lewis, et al. v. Ethicon, Inc.*, I concluded that Dr. Pence’s opinions on product labeling would “confuse and mislead the jury” because the state law claims of failure to warn no longer existed in the case. 2:12-cv-4301, 2014 WL 186872, at *19 (S.D. W. Va. Feb. 3, 2014). Here, however, the failure to warn claim is still pending, and so my conclusions in *Lewis* are inapposite on this point.

assertion that BSC's labeling fell short of the standard of care, and instead, she simply insists that BSC "should have gone further." (BSC's Mem. in Supp. of its Mot. to Exclude the Ops. and Test. of Peggy Pence ("BSC's Mem. re: Pence") [Docket 97], at 8 (quoting Pence Dep. [Docket 97-3], at 328:3)). In response, the plaintiffs point to Dr. Pence's reliance on medical publications and the FDA's Manufacturer and User Facility Device Experience database as evidence that Dr. Pence supported her opinions with authority. (*See* Pence Report [Docket 97-1], at 49–50).

Again, the reasoning in *Sanchez* reflects the court's view of this issue as presented here, and I **ADOPT** the *Sanchez* ruling as quoted below:

Indeed, Dr. Pence cites to various publications and data throughout her report. However, the information she references—literature and data on the reported complications associated with Pinnacle mesh—does not go to the heart of her opinion—that BSC failed to meet the “standard of care required of a medical device manufacturer” in its deficient labeling of its product. (*Id.* at 63). In other words, although this authority demonstrates that complications occurred, it does not provide any guidance as to whether these complications should have been included as warnings in the Pinnacle's IFU. Eliminating this peripheral information, Dr. Pence is left with *ipse dixit* sources like “the standard of care” (*id.*) and “a matter of ethics” (*id.* at 61), both of which fall short of *Daubert*'s reliability prong. *See Daubert*, 509 U.S. at 594 (explaining the importance of ascertainable “standards” to govern the expert's methodology in reaching his opinion).

Dr. Pence also utilizes FDCA provisions and FDA regulations to craft criteria for the information that should be included in medical device labeling. (*See* Pence Report [Docket 118-1], at 62 n.257–59, 63 n.260–61). As explained above, this may very well be relevant to the state law claim of failure to warn. *Daubert*, however, advises courts to keep in mind the other rules of evidence when evaluating expert testimony. *See Daubert*, 509 U.S. at 595 (“Throughout, a judge assessing a proffer of expert scientific testimony under Rule 702 should also be mindful of other applicable rules. . . .”). Rule 403, which permits exclusion of relevant evidence “if its probative value is substantially outweighed by danger of unfair prejudice, confusion of the issues, or misleading the jury,” Fed. R. Evid. 403, carries particular significance in *Daubert* decisions because “[e]xpert evidence can be both powerful and quite misleading.” *Daubert*, 509 U.S. at 595 (internal quotations omitted). Here, expert testimony about the requirements of the FDCA, which are not at issue in this case, could lead to more confusion about

the failure-to-warn claim than enlightenment. The jury might think that the FDA regulations *govern* warning requirements in [West Virginia], whereas Dr. Pence is actually using the FDA regulations as a *model* for the contents of labeling materials. Given that the probative value of expert testimony on FDA requirements is substantially outweighed by the risk of jury confusion, I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D. W. Va. 2014) (agreeing that "alleged shortcomings in FDA procedures are not probative to a state law products liability claim") (internal quotations omitted).

In sum, the only basis for Dr. Pence's opinions on the adequacy of BSC's product labeling is violation of the FDCA and FDA regulations. Such a violation, however, is not probative to the claims at issue. Moreover, asserting a violation of the FDCA is a legal conclusion, not an expert opinion. Accordingly, Dr. Pence's opinion testimony on BSC's labeling practices, both in the IFU and the patient brochure, is **EXCLUDED**.

Sanchez, 2014 WL 4851989, at *35–36.

4. Opinion on Post-market Vigilance

In her last opinion, Dr. Pence proffers that BSC "deviated from the standard of care by its failure to report to [the] FDA a number of adverse events that met the criteria for Medical Device Reporting, rendering the Obtryx and Pinnacle devices misbranded as a result of failure to furnish information requested under Section 519 of the FDCA." (*See Pence Report [Docket 97-1]*, at 83). BSC argues that whether BSC "reported adverse events to the FDA has no bearing on whether Boston Scientific provided adequate warnings or whether the Pinnacle was defective." (*See BSC's Mem. re: Pence [Docket 97]*, at 9).

For the reasons explained in *Sanchez*, I agree with BSC.

Dr. Pence cites to FDA public health notifications, the FDA's corporate warning letter to BSC, and the FDCA's Medical Device Reporting regulations. Contrary to the plaintiffs' assertions, however, the FDCA's reporting requirements and BSC's alleged violation of them have minimal relevance. First, the plaintiffs have not brought any claims concerning the FDCA. Second, even if an explanation of BSC–FDA communications could shed light on the state law claims at issue, testimony on whether or not BSC complied with the FDCA would constitute an

impermissible legal conclusion rather than an expert opinion. And finally, . . . opinion testimony on the labyrinth of reporting regulations within the FDCA has little probative value compared to the substantial risk of jury confusion, particularly when both parties agree that “whether, how, and when BSC communicated safety information to the FDA is irrelevant.” (See Pls.’ Resp. re: Pence [Docket 122], at 17). Accordingly, . . . I **EXCLUDE** Dr. Pence’s opinions on post-market vigilance.

Sanchez, 2014 WL 4851989, at *36.

In conclusion, Dr. Pence can testify on pre-market testing, but her opinions on the adequacy of product labels and the reporting of adverse events to the FDA are **EXCLUDED**. As such, BSC’s Motion to Exclude Peggy Pence [Docket 96] is **GRANTED IN PART** and **DENIED IN PART**.

G. Motion to Exclude the Testimony of Dr. Mark Slack & Motion for Leave to File Supplemental Brief to Its Motion to Exclude Testimony of Dr. Mark Slack

Pending before the court are two motions by BSC regarding Dr. Mark Slack. The first [Docket 98] is a typical *Daubert* motion seeking to limit the opinions of Dr. Slack. The second [Docket 147] is a Motion for Leave to File Supplemental Brief to Its Motion to Exclude the Testimony of Dr. Mark Slack (“Motion for Leave”). In its Motion for Leave, BSC seeks to file a supplemental brief in light of Dr. Slack’s deposition, which had not taken place at the time of the original filing. However, because I **GRANT** BSC’s *Daubert* motion regarding Dr. Slack, as discussed below, no further briefing is necessary. Accordingly, BSC’s Motion for Leave is **DENIED**.

Dr. Slack is a consultant gynecologist and practicing urogynecologist in the United Kingdom. (Slack Report [Docket 99-1], at 1). Eighty-five percent of his daily practice involves dealing with the management of prolapse and incontinence. (*Id.*). Dr. Slack opines on the following topics as they relate to BSC’s mesh products: (1) pelvic floor anatomy and pelvic floor

dysfunction; (2) research and testing necessary for marketing and launch; (3) directions for use (“DFU”); and (4) physician training. (*Id.* at 5). BSC does not challenge Dr. Slack’s opinions regarding pelvic floor anatomy and pelvic floor dysfunction. BSC seeks to exclude Dr. Slack’s opinions on the remaining three topics because he is unqualified and fails to offer any reliable basis for his opinions. (BSC’s Mem. of Law in Supp. of its Mot. to Limit the Ops. & Test. of Mark Slack, M.D. [Docket 99], at 1–2). Additionally, the defendant contends that Dr. Slack’s report largely consists of improper expert testimony including: (1) narrative testimony; (2) conclusory statements regarding BSC’s state of mind; and (3) improper legal conclusions. (*Id.* at 2). As discussed below, Dr. Slack’s opinions should be excluded to the extent challenge and, accordingly, BSC’s motion to limit his opinions is **GRANTED**.

Much of Dr. Slack’s export report is a narrative review of corporate documents and his opinions are riddled with improper testimony regarding BSC’s state of mind and legal conclusions. (*See, e.g.*, Slack Report [Docket 99-1], at 13 (“Boston Scientific had an obligation to critically evaluate all of the potential complications and their consequences, in order to adequately warn physicians and patients. Boston Scientific did not satisfy their obligation by failing to study the grave consequences of attempting to treat mesh complications, and did not recognize or admit that the devices might introduce too much risk and should be studied before being marketed.”); *id.* at 16 (“Boston Scientific recognized the problems created by not having clinical data supporting the use of its products.”); *id.* at 19 (“In March 2007, the Boston Scientific clinical affairs department knew that if a woman suffered erosion or exposure of mesh the consequences could be severe including the need for follow up invasive surgery. This potential significant risk, with the root cause being the mesh itself, was foreseen by Boston

Scientific before marketing a single Pinnacle device.”); *id.* at 20 (“It appears that as early as 2003, Boston Scientific knew that there could be problems with the polypropylene mesh.”); *id.* at 21 (“Boston Scientific was aware of the significant role physician training has with respect to patient safety.”); *id.* at 22 (“Boston Scientific knew prior to the time these products were placed on the open market that surgeon technique could impact surgical outcome.”); *id.* at 23 (“It was Boston Scientific’s goal to create a standardized, reproducible surgical technique.”). In fact, an entire section of Dr. Slack’s report is about how BSC possessed the same knowledge as the scientific community regarding the safety and efficacy of pelvic floor products before introducing their product into the market. (*Id.* at 10–12).

Dr. Slack also opines on what course of action BSC should have taken; however, the majority of Dr. Slack’s opinion simply recites what BSC did or did not do. *See In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (“An expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based on the record of evidence.”). As I previously discussed, expert opinions on BSC’s knowledge, state of mind, and legal conclusions are not appropriate subjects of expert testimony. Therefore, these opinions are **EXCLUDED**, and BSC’s Motion to Exclude the Testimony of Dr. Slack [Docket 98] is **GRANTED**.⁹

H. Motion to Exclude the Testimony of Dr. R. Brian Raybon

Dr. Raybon is a board certified physician in obstetrics and gynecology, specializing in female pelvic and reconstructive surgery since 1998. (Raybon Report [Docket 101-1], at ¶ 1). BSC brings two challenges to Dr. Raybon’s testimony. First, BSC contends that Dr. Raybon’s

⁹ Because Dr. Slack’s impermissible state of mind opinions permeate his entire expert report, I need not address the remainder of BSC’s specific objections based on reliability.

general causation opinions regarding the properties of mesh lack the support of reliable facts or data. Second, BSC argues that Dr. Raybon did not conduct a proper differential diagnosis in his specific causation assessment of Ms. Dotres. Thus, BSC asks this court to exclude both the general and specific causation testimony of Dr. Raybon. For the following reasons, I **GRANT IN PART** and **DENY IN PART** BSC's motion to exclude. [Docket 101].

1. General Causation Opinions

Dr. Raybon provides several general causation opinions regarding the clinical effects of the Pinnacle product. He opines that there is an "ongoing irritation of nerves from the body's reaction to the Pinnacle mesh"; that Pinnacle mesh causes "chronic inflammation," leading to "an environment where pain receptors are repeatedly stimulated"; and that Pinnacle mesh creates a "toxic environment" resulting in the loss of nerve function. (Raybon Report [Docket 101-1], at ¶ 5). BSC argues that these opinions have "no scientific basis and should be excluded under *Daubert*" as *ipse dixit* opinions. (BSC's Mem. in Supp. of Mot. to Exclude the Ops. and Test. of Dr. Brian Raybon [Docket 101] ("BSC's Mem. re: Raybon"), at 5).

BSC compares Dr. Raybon's opinion to that of Dr. Zolnoun, the plaintiff's expert in *In re Bard*. I excluded Dr. Zolnoun's general causation opinion because it centered on "nothing more than her personal, unscientific observations and opinion that 'it's obvious' that mesh arms are sharp and can serrate or tear nerves." *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 604 (S.D. W. Va. 2013). According to BSC, Dr. Raybon's general causation opinions similarly have no scientific basis and arise solely from his own observations, and so his testimony should be excluded.

In response, the plaintiffs contend that Dr. Raybon's expert opinion is similar to Dr.

Steege's opinion in *Huskey v. Ethicon, Inc.* and *Edwards v. Ethicon, Inc.*, whose general causation opinions I allowed, even though he had never performed a mesh procedure, conducted studies on implantation of mesh, or examined the biomechanical properties of mesh. *Huskey v. Ethicon, Inc.*, 2:12-cv-05201, 2014 WL 3362264, at *14–15 (S.D. W. Va. July 8, 2014); *Edwards v. Ethicon, Inc.*, 2:12-cv-09972, 2014 WL 3361923, at *5 (S.D. W. Va. July 8, 2014). In those cases, I found that Dr. Steege's extensive knowledge compensated for his lack of experience with pelvic mesh. *See Huskey*, 2014 WL 3362264, at *14 (finding that Dr. Steege's report and curriculum vitae demonstrated his knowledge of "the etiology of problems associated with the implantation of mesh products in gynecological surgery"). In an attempt to analogize Dr. Raybon's qualifications with that of Dr. Steege's, the plaintiffs recount Dr. Raybon's extensive experience with pelvic mesh. (*See* Pls.' Opp'n to BSC's Mot. to Exclude the Ops. and Test. of Dr. Brian Raybon [Docket 128], at 4–6 (outlining Dr. Raybon's curriculum vitae and deposition testimony about his qualifications)). From this list of experiences and training, the plaintiffs assert that Dr. Raybon should be allowed to render expert opinions on the etiology of complications associated with the Pinnacle device.

Acknowledging Dr. Raybon's demonstrated experience as a physician, I nevertheless find that his general causation opinions do not withstand the Supreme Court's directives in *Daubert*. First, Federal Rule of Evidence 702 allows a witness to provide expert opinion testimony only to the extent that the testimony draws from the expert's knowledge and expertise. Fed. R. Evid. 702 advisory committee notes. In *Edwards* and *Huskey*, for example, Dr. Steege had an extensive and demonstrated background in the causes of pelvic pain. *Edwards*, 2014 WL 3361923, at *4–5. He specialized in the etiology of chronic pelvic pain, vaginal pain, and sexual pain, and he taught

courses on the subject. *See Edwards*, 2014 WL 3361923, at *5. Thus, Dr. Steege’s testimony about the nerve trauma that can result from mesh implantation was proper. *Id.* Dr. Raybon’s opinion testimony, on the other hand, goes beyond his experience with pelvic mesh. He is not a specialist in the etiology of pelvic and vaginal pain, and his awareness of any relationship between nerve trauma and mesh products is limited to his experience in diagnosing fifteen to twenty post-implantation patients. Accordingly, Dr. Raybon’s knowledge, though extensive with respect to the mechanics of pelvic surgery, does not qualify him to opine on the cause of nerve trauma in the pelvis. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (“A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.”).

Furthermore, Dr. Raybon’s general causation opinions do not satisfy the reliability requirements of *Daubert*. Dr. Raybon’s opinion that the Pinnacle mesh causes nerve irritation, chronic inflammation, and stimulation of pain receptors is based solely on his experience as a physician. In his deposition, Dr. Raybon concedes that he did not “reference any articles” in making his opinion because his testimony is based on “knowledge and opinion [he has] accumulated over the last several [] years.” (Raybon Dep. [Docket 128-3], at 161:15–18). Dr. Raybon performed no tests or experiments to come to his conclusions nor has he submitted any relevant work to peer review. This *ipse dixit* does not survive *Daubert*’s scrutiny. *See Gen. Elec. Co.*, 522 U.S. at 146 (“[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.”). Accordingly, I **EXCLUDE** Dr. Raybon’s general causation testimony about the etiology of Pinnacle mesh. *See Brown v. Burlington N. Santa Fe Ry. Co.*, No. 13-2102, 2014 WL

4257854, at *9 (7th Cir. Aug. 29, 2014) (“[E]xperience without reliable, testable methodology is not sufficient.”).

BSC also objects to Dr. Raybon’s testimony that “at least 30% of [his] patients developed complications related to Pinnacle mesh, including mesh extrusions and pain.” (BSC’s Mem. re: Raybon [Docket 101], at 6). This testimony fails under the same rationale described above. Dr. Raybon provided no objective data to back up this assertion and instead simply relied on memory.

Q: In order to generate this report, did you go back and try to count how many women you actually used the Pinnacle in?

A: No This is based on memory.

(Raybon Dep. [Docket 128-3], at 145:19–24). Based on his memory, Dr. Raybon stated that he used Pinnacle on fifteen to twenty-five patients, and he “sat on” a guess of twenty patients when calculating the 30% complication rate. (*Id.* at 146:3). Dr. Raybon conceded that in calculating this percentage, he did not review medical records of any sort but was “very confident” that six of his estimated twenty patients had complications with Pinnacle mesh. (*Id.* at 148:10).

I have previously rejected testimony of this sort that arbitrarily states a complication rate without explaining the method of doing so. *See Lewis, et al. v. Ethicon, Inc.*, 2:12-MD-02327, 2014 WL 186872, at *8 (S.D. W. Va. Jan. 15, 2014) (excluding the error rate testimony of Dr. Klinge). Expert opinion must “be connected to data by something more than the ‘it is so because I say it is so’ of the expert.” *Holesapple v. Barrett*, 5 F. App’x 177, 180 (4th Cir. 2001). Accordingly, I **EXCLUDE** Dr. Raybon’s testimony on the complication rate of his patients.

2. Specific Causation Opinions

Dr. Raybon also provides a case-specific assessment of Ms. Dotres in his expert report.

[Docket 101-1]. After reviewing the medical history and deposition testimony of Ms. Dotres, Dr. Raybon opines that “[t]he voiding dysfunction, pain and defecatory problems that . . . [Ms. Dotres] currently experiences are, to a reasonable degree of medical certainty, due to the ongoing irritation of nerves from the body’s reaction to the Pinnacle mesh.” (Raybon Report [Docket 101-1], at ¶ 5). BSC argues that this court should exclude Dr. Raybon’s specific causation testimony because he did not conduct a proper differential diagnosis in reaching his conclusion.

BSC first asserts that Dr. Raybon’s differential diagnosis is inadequate because he did not examine Ms. Dotres or interview her, instead basing his opinion solely on review of her medical history and her deposition. Although performance of physical examinations typically suggests that the differential diagnosis is reliable, *see Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999), in some instances, “a physician may reach a reliable differential diagnosis without personally performing a physical examination.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001). Thus, Dr. Raybon’s failure to physically examine Ms. Dotres does not, in itself, render his differential diagnostic unreliable, especially considering that he reached his opinion by studying the records of other medical practitioners who examined Ms. Dotres. (See Raybon Report [Docket 101-1], at ¶ 6 (listing the records Dr. Raybon reviewed in reaching his opinion, including the medical findings of four doctors who examined Ms. Dotres)); *see also Kannankeril v. Terminix Int’l, Inc.*, 128 F.3d 802, 807 (3d Cir. 1997), *as amended* (Dec. 12, 1997), (“[A] physician may reach a reliable differential diagnosis without himself performing a physical examination, particularly if there are other examination results available.”).

Having found that Dr. Raybon’s failure to physically examine Ms. Dotres does not per se eliminate his specific causation testimony, I move to the “core” of differential diagnosis—“the

requirement that experts at least consider alternative causes” of the plaintiff’s medical condition and rule out each alternative cause as the source of the claimed injury. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 759 (3d Cir. 1994). Dr. Raybon addresses two alternative causes to Ms. Dotres’s current defecation and urination problems: (1) preexisting constipation; and (2) preexisting back pain.

First, Dr. Raybon asserts that because Ms. Dotres had no defecatory problems prior to the mesh implantation, the mesh must have caused her current difficulties. (Raybon Report [Docket 101-1], at ¶ 5). BSC argues that this statement contradicts Ms. Dotres’s deposition, in which she acknowledged that she had “constipation” prior to her mesh implant surgery. (Dotres Dep. [Docket 101-3], at 142:7–9). Additionally, BSC emphasizes Dr. Raybon’s concession that he could not “rule out” the worsening of Ms. Dotres’s constipation as a progression of her pre-surgery defecatory problems as opposed to a consequence of the mesh. (*See* Raybon Dep. [Docket 101-2], at 186:4–9).

Second, Dr. Raybon eliminated spinal stenosis, a condition in which the spinal cord puts pressure on the nerves exiting the spine, as a cause of Ms. Dotres’s current problems with urination and pelvic pain. (*See id.* at 166:30–167:2 (defining spinal stenosis)). He reached this conclusion from reviewing Ms. Dotres’s medical records, which contained “no objective data to support this diagnosis [or any] indications that Ms. Dotres has motor or sensory deficit in her legs,” which is a symptom usually associated with a spinal injury. (Raybon Report [Docket 101-1], at ¶ 5). BSC disputes this opinion because Dr. Raybon conceded at his deposition that he could not “rule out her back pain as a cause of her complained nerve impingement and incontinence issues.” (BSC’s Mem. re: Raybon [Docket 101], at 8).

These challenges to Dr. Raybon's specific causation opinions go to credibility, not admissibility. In reviewing a *Daubert* objection, the court's role is to conduct "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid." *Daubert*, 509 U.S. at 592. Here, Dr. Raybon thoroughly examined Ms. Dotres's medical records, considered possible causes for her current symptoms, and determined that her records "do not indicate any cause other than the Pinnacle mesh." (Raybon Report [Docket 101-1], at ¶ 5). I have previously accepted this methodology as reliable under *Daubert*. See *Tyree et al. v. BSC*, No. 2:12-cv-08633, 2014 WL 5320566, at *52 (S.D. W. Va. Oct. 17, 2014) (concluding that Dr. Rosenzweig's specific causation testimony is not excluded under *Daubert* because he "adequately considered and eliminated alternate causes" of the plaintiff's symptoms after reviewing her medical records).

Furthermore, an expert's failure to completely "rule out" a possible alternative cause of a plaintiff's illness should not necessarily lead to exclusion under *Daubert*, "unless the expert can offer *no* explanation for why [he] has concluded an alternative cause . . . was not the sole cause." *Westberry*, 178 F.3d at 265 (internal quotations omitted). Dr. Raybon, although admitting he could not completely eliminate pre-surgery constipation or spinal stenosis as causes of Ms. Dotres's current problems, provided specific reasons for his opinion that the mesh is the most probable source. Dr. Raybon explained that the mesh is most likely responsible for Ms. Dotres's defecatory problems because the increased constipation "happened after the surgery," at the same time her other symptoms appeared. (Raybon Dep. [Docket 101-2], at 185:21–23). "[A] temporal relationship between exposure to a substance and the onset of a disease or worsening of symptoms can provide compelling evidence of causation," especially considering that Dr.

Raybon has reviewed all of the relevant medical records that might indicate otherwise. *Westberry*, 178 F.3d at 265. In addition, Dr. Raybon eliminated spinal stenosis because “there are no indications that Ms. Dotres has motor or sensory deficit in her legs,” which is a common symptom of spinal stenosis. (Raybon Report [Docket 101-1], at ¶ 5). Dr. Raybon’s report and his deposition testimony demonstrate that Dr. Raybon has considered alternative causes and reasoned that while he cannot absolutely rule out these causes, he can exclude them as the “most likely” cause. This methodology satisfies *Daubert*. See *Westberry*, 178 F.3d at 262 (concluding that a differential diagnosis is accomplished by “determining which of those [alternative causes] that cannot be excluded is the most likely”).

In sum, BSC’s arguments against Dr. Raybon’s specific causation testimony concern the accuracy of his differential diagnosis. Such arguments go to “the weight that the jury should give the expert’s testimony and not the admissibility of that testimony.” *Id.* at 265. At trial, BSC can certainly expound on the accuracy of Dr. Raybon’s exclusion of progressed constipation and back pain as a cause for Ms. Dotres’s current complaints, but for purposes of *Daubert*, I **FIND** Dr. Raybon’s methodology to be reliable. Accordingly, BSC’s motion on specific causation point is **DENIED**.

BSC’s Motion to Exclude the Opinions and Testimony of Dr. Raybon [Docket 100] is therefore **GRANTED IN PART** (with respect to general causation opinion testimony) and **DENIED IN PART** (with respect to specific causation opinion testimony).

I. Motion to Exclude the Testimony of Linda Kiley, M.D.

BSC moves to exclude the testimony of Linda Kiley, M.D. Dr. Kiley is board certified in Obstetrics and Gynecology and in the subspecialty of Female Pelvic Medicine and

Reconstructive Surgery. (*See* Kiley Report [Docket 103-1], at 9). She is the treating physician who performed Ms. Eghnayem's Pinnacle removal surgery in 2012. (*See id.* at 6). Dr. Kiley seeks to offer general causation opinions on the properties and complications of transvaginal mesh and specific causation opinions regarding Ms. Eghnayem's injuries. BSC argues that Dr. Kiley's general causation opinions should be excluded because she is unqualified to opine as to the properties of transvaginal POP mesh and because her general causation opinions lack a scientific basis. (*See* Def. BSC's Mem. of Law in Supp. of Its Mot. to Exclude the Ops. & Test. of Linda Kiley, M.D. ("BSC's Mem. re: Kiley") [Docket 103], at 2). BSC also alleges that Dr. Kiley's specific causation opinions should be excluded because she failed to perform a proper differential diagnosis. (*See id.*).

1. General Causation Opinions

BSC argues that Dr. Kiley is unqualified to offer general causation opinions as to the properties of transvaginal mesh and its complications and that her general causation opinions lack a reliable scientific basis. In her expert report, Dr. Kiley states that:

The reasons I do not implant polypropylene transvaginal mesh for pelvic organ prolapse are (1) transvaginal mesh does not provide an anatomical solution for pelvic organ prolapse repair, (2) transvaginal placement permits the development of biofilm¹⁰ and inflammation due to the contamination of the polypropylene mesh, and (3) I believe the resulting biofilm is the basis for the symptoms and complications associated with the polypropylene synthetic mesh.

(Kiley Report [Docket 103-1], at 4). BSC states that Dr. Kiley "also offers opinions that Pinnacle mesh can cause infection, nerve entrapment, shrinkage and scarring of mesh." (BSC's Mem. re: Kiley [Docket 103], at 6 (citing page of Dr. Kiley's expert report which states that Ms.

¹⁰ In its memorandum, BSC states that "[t]he parties have agreed that Dr. Kiley will not offer general or specific causation opinions regarding biofilm." (BSC's Mem. re: Kiley [Docket 103], at 6, n.4). Therefore, I will not address the reliability and relevancy of Dr. Kiley's biofilm opinions.

Eghnayem’s “pelvic pain, dyspareunia, bleeding with intercourse, urinary incontinence, vaginal tenderness and mesh erosion were caused by infection, inflammation, nerve entrapment, shrinkage, and scarring of the mesh”)).¹¹ I will address the qualifications and reliability arguments below.

a. Qualifications

Dr. Kiley is an accomplished OB/GYN doctor. (*See* Kiley Report [Docket 103-1], at 9–12 (Dr. Kiley’s curriculum vitae)). She asserts that her “background, training and experience all qualify [her] to review and comment on the area of surgical meshes and slings used in tissue repair, including Boston Scientific pelvic floor reconstructive mesh and stress urinary incontinence slings, and the complications associated with such products.” (*Id.* at 4). Dr. Kiley has more than 20 years of experience. (*See id.* at 3). She has performed more than 10,000 surgeries, including an average of 2 major procedures and 5 minor procedures each week. (*See id.*). Approximately half of her patients seek her care “due to complications associated with prior gynecologic surgery, prolapse, incontinence, fistulas and mesh and sling related injuries[,]” and she performs surgeries to treat POP, including procedures using BSC products. (*Id.* 3–4). Although she has performed more than 500 vaginal prolapse repairs, she has “never used polypropylene transvaginal mesh kits for the repair of [POP].” (*Id.* at 4). However, over the past six years, Dr. Kiley has removed an average of one polypropylene mesh sling or POP device

¹¹ BSC’s citation here to Dr. Kiley’s expert report seems to refer to her specific causation opinions about Ms. Eghnayem. In fact, BSC cites to this same page when discussing Dr. Kiley’s specific causation opinions. (*See* BSC’s Mem. re: Kiley [Docket 103], at 7). Even so, the plaintiff does not refute BSC’s assertion that Dr. Kiley seeks to opine as to general causation. (*See* Pl.’s Resp. to Def. BSC’s Mot. to Exclude the Test. of Linda Kiley, M.D. (“Pl.’s Resp. re: Kiley”) [Docket 133], at 8). Moreover, Dr. Kiley writes in her expert report that her “background, training and experience all qualify [her] to review and comment on the area of surgical meshes and slings used in tissue repair, including Boston Scientific pelvic floor reconstructive mesh and stress urinary incontinence slings, and the complications associated with such products.” (Kiley Report [Docket 103-1], at 4). Therefore, I will proceed with the assumption that Dr. Kiley seeks to offer general causation opinions.

each month from her patients. (*Id.*).

Dr. Kiley may be qualified to opine as to the properties of polypropylene transvaginal mesh and its complications. However, I need not make this determination because I find her general causation opinions to be unreliable. To the extent that BSC challenges Dr. Kiley's general causation opinions as to biomaterials topics, BSC's motion is **DENIED AS MOOT** because the plaintiff concedes that she "has not and does not intend to offer [Dr. Kiley] to opine regarding such matters." (Pl.'s Resp. re: Kiley [Docket 133], at 8).

b. Reliability

BSC also challenges the reliability of Dr. Kiley's general causation opinions. In particular, BSC argues that her opinions lack a scientific basis.

Dr. Kiley states that, "[i]n order to more fully understand how to deal with the complications of these systems and remove them, [she has] observed numerous sling and mesh insertion procedures by [her] colleagues" and that she has "studied textbooks, publications, DFU's, surgical videos, cadaver dissections and countless operative reports as part of [her] study of sling and mesh surgeries." (Kiley Report [Docket 103-1], at 4). In forming all of her opinions, Dr. Kiley states that she "considered the scientific literature, the deposition transcript of Amal Eghnayem, [her] care and treatment of Amal Eghnayem, including Mrs. Eghnayem's revision surgery which [she] performed on August 29, 2012 and [her] overall experience." (*Id.*).

Despite these assertions, I am unable to identify a single scientific study cited in Dr. Kiley's expert report. (*See* Kiley Report [Docket 103-1]). Even her relied upon list contains no scientific studies. (*See id.* at Appendix B (naming only the following five materials: (1) "Deposition and all exhibits – Amal Eghnayem, taken May 19, 2014"; (2) "Pinnacle DFU

2008[;]” (3) “Good Samaritan Medical Center, Medical Records”; (4) “Premier Family Health, P.A., Medical Records”; (5) “OB GYN Specialists of the Palm Beaches, Medical Records”).

In her deposition, Dr. Kiley notes some scientific sources that she has considered. (*See, e.g.,* Kiley Dep. [Docket 133-2], at 7:18–8:6, 8:19–9:16, 46:7–11, 49:13–16, 77:14–20 (noting a dissertation on biofilms she found the night before her deposition, “some printouts of abstracts and articles that [she] was aware of,” Dr. Gouda’s report and some of his references, the *Rosenblatt* study, the *Nygaard* study and stating that she relies on “medical literature” and textbooks in her clinical practice). Nevertheless, Rule 26 plainly states that, “[u]nless otherwise stipulated or ordered by the court[,]” an expert’s written report “must contain . . . a complete statement of all opinions the witness will express *and the basis and reasons for them*” and “*the facts or data considered by the witness* in forming them” Fed. R. Civ. Proc. 26(a)(2)(B)(i)–(ii) (emphasis added). Dr. Kiley’s report fails to meet these requirements, and the plaintiffs do not provide any justification for her omissions. “Proposed testimony must be supported by appropriate validation—*i.e., ‘good grounds’ based on what is known.*” *Daubert*, 509 U.S. at 590. Without information about which studies Dr. Kiley relied upon in forming each of her opinions in her report, I am unable to conclude whether her opinions are based on a reliable method. Therefore, Dr. Kiley’s general causation opinions are **EXCLUDED**.

2. Specific Causation Opinions

Dr. Kiley also seeks to offer specific causation opinions as to Ms. Eghnayem. In particular, Dr. Kiley opines that “to a reasonable degree of medical certainty, the injuries sustained by Amal Eghnayem are caused by the Boston Scientific Pinnacle system. The pelvic pain, dyspareunia, bleeding with intercourse, urinary incontinence, vaginal tenderness and mesh

erosion were caused by infection, inflammation, nerve entrapment, shrinkage, and scarring of the mesh.” (Kiley Report [Docket 103-1], at 6). BSC argues that Dr. Kiley’s specific causation opinions are unreliable because she failed to conduct a proper differential diagnosis.

“[A] reliable differential diagnosis provides a valid foundation for an expert opinion.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999). It “typically, though not invariably, is performed after ‘physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests,’ and generally is accomplished by determining the possible causes for the patient’s symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.” *Id.* at 262 (citation omitted). BSC alleges that Dr. Kiley failed to properly rule out Ms. Eghnayem’s pre-implantation pelvic pain, the care of treating physicians, and “patient-specific factors” such as “genetics or co-morbidities.” (BSC’s Mem. re: Kiley [Docket 103], at 8; *see* Kiley Dep. [Docket 103-2], at 112:1–9 (noting Ms. Eghnayem’s pre-implantation “vaginal pressure and pain that radiated to her back”); *see id.* at 112:14–16 (noting Ms. Eghnayem’s pre-implantation complaints of “painful intercourse”)).

Dr. Kiley’s expert report reveals that she reviewed Ms. Eghnayem’s medical history, conducted an exam of Ms. Eghnayem, and treated her. (*See* Kiley Report [Docket 103-1], at 4–6). Dr. Kiley testifies that she always performs a differential diagnosis on all of her patients:

A: I always have a differential diagnosis for every patient I see who comes in with a complaint . . .

Q: Okay. So tell us how you went about that process.

A: Well, when a patient presents as she – as she presents her history to me, I start to think about what could be the cause of her problems. That’s the differential diagnosis. It’s an automatic process that takes place as a

physician when I evaluate someone. So a history is what begins the differential diagnosis. I have pain. I feel there's something, my husband has pain, I start to think about, well, what – what could be the cause of that. Then I do the examination. I see what I see. That narrows my differential diagnosis significantly. We start with a list of five or ten things, we go down to one or two things, all right, and then eventually treatment plan based on differential diagnosis, cancelling [sic] of the patient is undertaken and then post-operatively we get what we get. We get our confirmation or not.

(Kiley Dep. [Docket 133-2], at 167:22–168:17). Contrary to BSC's assertions, Dr. Kiley did consider Ms. Eghnayem's pre-existing pain during the course of treatment:

Q: Okay. You were in a unique position in this case in the sense that not only have you rendered this opinion about the relation of her symptoms to the product from having a chance to obviously look at her records but you also cared for her obviously; correct?

A: Yes.

Q: You also had the benefit of being the physician who actually did the revision surgery on her; correct?

A: That's correct.

Q: How did that help you in terms of making or drawing these conclusions about the relationship between her symptoms and the product?

A: Well, simply because looking at her overall history and conducting her exam, conducting her surgery and conducting her post-operative care allowed me to see the continuum. And there was a period of time before her surgery when she had distressful symptoms and they were fairly specific and they mostly centered around more vaginal laxity. She wanted to have a tighter vagina, some pressure, those kinds of things.

During the time that she had her implant, she had a different kind of pain and her husband had pain. Once that was removed, her symptoms improved.

My experience has shown that happens as a general rule when I see patients with mesh-related pelvic organ prolapse problems . . .

(*Id.* at 167:18–169:20). Dr. Kiley observed mesh erosion and exposure intraoperatively in Ms.

Eghnayem and provides an explanation as to how this erosion could have caused the pain the plaintiff and her husband experienced. (*See id.* at 170:16–171:15; Kiley Report [Docket 103-1], at 5–6). Also, during the 2012 removal procedure, Dr. Kiley “found significant scarring and vaginal varicosities in vessels *in the area of the Boston Scientific Pinnacle mesh.*” (Kiley Report [Docket 103-1], at 6 (emphasis added)). Dr. Kiley has placed a biologic graft in Ms. Eghnayem and states that she does not “believe that the biologic graft that was placed played any adverse role in her recovery” because the plaintiff’s symptoms have improved after the removal of her Pinnacle. (Kiley Dep. [Docket 133-2], at 170:3–15).

In sum, Dr. Kiley testifies:

Q: Okay. What is the basis of that opinion that the Boston Scientific Pinnacle system caused these symptoms and conditions in Ms. Eghnayem?

A: It’s based on the fact that she presented post-operatively with symptoms that were new and different from symptoms she had had previously and my physical examination of her, my evaluation of her preoperatively, intraoperatively, and post-operatively are – and observing how she has done long-term since her surgery and that she was vastly improved after the removal of the system is what my opinion is based on for her.

Q: Okay. So would it be a fair statement to say that this opinion that you’ve expressed that Ms. Eghnayem’s symptoms are related to the Boston Scientific Pinnacle system is based upon your care and treatment of her?

A: Yes.

Q: Is it based upon your overall clinical experience having cared for patients in the past with this condition?

A: Yes.

(*Id.* at 166:19–167:16 (counsel names and objections omitted)). Dr. Kiley’s diagnosis of Ms. Eghnayem is sufficiently reliable to survive *Daubert* scrutiny. I **DENY** BSC’s motion with respect to Dr. Kiley’s specific causation opinions.

Therefore, I **GRANT IN PART** (with respect to general causation opinion testimony) and **DENY IN PART** (with respect to specific causation opinion testimony) BSC's motion on Dr. Kiley [Docket 102].

J. Motion to Exclude the Testimony of Vladimir Iakovlev, M.D.

BSC seeks to exclude the opinions of Dr. Vladimir Iakovlev. Dr. Iakovlev is an anatomical pathologist and director of Cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, Canada. (Iakovlev Report [Docket 105-1], at 2). In his expert report, Dr. Iakovlev describes a study he participated in with Dr. Robert Bendavid beginning in 2012 to "analyze explanted mesh and . . . provide a correlation between pathological findings and clinical symptoms." (*Id.*). Based on this study, as well as his background in pathology, Dr. Iakovlev concludes "that women implanted with pelvic mesh devices are at an increased risk of suffering chronic and debilitating pelvic pain and dyspareunia as a result of the higher innervation of that anatomical region of the body compared to the anterior abdominal wall." (*Id.* at 3). BSC makes the following arguments against the admissibility of Dr. Iakovlev's opinions under *Daubert*: (1) his general causation opinions are unreliable; (2) his deformation opinions based on the "stretch test" are unreliable; (3) he is unqualified to opine on mesh design and deformation and his opinions are unreliable; (4) he is unqualified to opine on polypropylene degradation and his opinions are unreliable; and (5) he is unqualified to offer specific causation opinions and his opinions regarding Ms. Eghnayem are unreliable. (*See generally* BSC's Mem. of Law in Supp. of Its Mot. to Exclude the Ops. & Test. of Vladimir Iakovlev, M.D. ("BSC's Mem. re: Iakovlev") [Docket 105]). For the reasons

discussed below, BSC's motion [Docket 104] is **GRANTED IN PART** and **DENIED IN PART**.

1. Opinions Based on the Stretch Test

BSC challenges the reliability of Dr. Iakovlev's opinions drawn from his mechanical testing of BSC devices. Dr. Iakovlev performed a "stretch test" on BSC mesh to simulate forces acting on the device in the body and confirm his hypothesis that mesh deforms after stretching forces are applied to it. (*See* Iakovlev Report [Docket 105-1], at 12; *see also* Iakovlev Dep. [Docket 105-4], at 350). Dr. Iakovlev placed the mesh on a flat surface against a scale and secured the ends with clamps. (Iakovlev Dep. [Docket 105-4], at 345). Then, by pulling the clamps apart, he stretched the mesh to 120% of its original length. (*Id.*). Dr. Iakovlev observed permanent bowing, lengthening, and raised edges, which he opines is similar to the natural deformation that takes place inside the human body. (*See* Iakovlev Report [Docket 105-1], at 12).

In particular, BSC makes the following arguments as to why Dr. Iakovlev's testing was methodologically flawed: (1) his testing method was not based on any testing standards and did not have a written protocol; (2) he did not regulate or measure how much force he applied to the mesh samples; (3) he set clamps on the mesh, but cannot provide measurements; (4) he intended to stretch the mesh to reach 120% of the original length, but does not know how he arrived at that result or how to repeat the test; (5) he could not describe or comprehend how he controlled his test for confirmation bias; (6) he does not know whether mesh responds to stretching with clamps the same way it does when implanted in the human body, nor has he done mechanical testing on mesh in the body; (7) he cannot validate that stretching mesh on a machine replicates

the behavior of mesh in the body because he only measured unilateral forces, and not forces from multiple directions or the amount of force used; and (8) he has no knowledge of any general acceptance of his methodology in the scientific community. (BSC's Mem. re: Iakovlev [Docket 105], at 7). BSC's objections can be divided into two categories: (1) testing standards and (2) in vivo environment.

I have previously reviewed the opinion testimony of Dr. Iakovlev under *Daubert*. See *Tyree, et al. v. Boston Scientific, Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *39–43 (S.D. W. Va. Oct. 17, 2014). The parties in this case assert the same arguments regarding the reliability of Dr. Iakovlev's stretch test that I addressed in *Tyree*. To the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. The *Tyree* excerpts quoted below are to explicate the conclusions the court reaches on the reliability of Dr. Iakovlev's stretch test:

a. Testing Standards

Many of BSC's arguments incorporate Dr. Iakovlev's failure to adhere to testing standards or a written protocol. In his deposition, Dr. Iakovlev states that he developed the stretch test method; however, he failed to follow a written protocol other than the brief description included in his expert report. (Iakovlev Dep. [Docket 225-3], at 345). When describing the methodology he employed, Dr. Iakovlev admits that he did not wear gloves, clean or sterilize the mesh, or use machinery to regulate the amount of force exerted. (*Id.* at 347–48). Dr. Iakovlev insists that because the criterion for the test was length rather than force, the regulation of force was irrelevant. (*Id.* at 348). Nevertheless, Dr. Iakovlev readily admits that he developed and performed the stretch test himself, without taking care to standardize his method or the results. (*Id.* at 345, 350). Additionally, Dr. Iakovlev has no knowledge of whether his methodology is generally accepted in the medical community. (*Id.* at 350). Finally, when asked how he can be sure his results were not caused by the way he pulled the mesh, Dr. Iakovlev's only response is that the stretch test was a simulation, which I **FIND** insufficient to establish reliability. (*Id.* at 351–52).

b. In Vivo Environment

BSC's remaining two arguments are in regard to Dr. Iakovlev's failure to replicate an in vivo environment. Although Dr. Iakovlev states that he performed the stretch test to simulate forces acting on the device in the body, BSC contends that Dr. Iakovlev has no way of knowing whether mesh responds to stretching with clamps the same way it does when implanted inside of a woman. (Def.'s Mem. re: Iakovlev [Docket 226], at 7). BSC further argues that Dr. Iakovlev's tests failed to replicate the forces in the female pelvic floor because he measured uniaxial forces, while the forces in the female pelvic floor are generally multi-directional. (*See id.*).

The mere fact that Dr. Iakovlev's study was uniaxial does not alone render his methodology unreliable; however, the fact that he did not account for multi-directional forces inside of the female pelvis weighs heavily against admissibility. Much like his response to BSC's question regarding confirmation bias, when asked about the way mesh responds inside and outside of the body, Dr. Iakovlev states that "the assumption is that if the forces are similar, the behavior will be similar. That's a limitation of all experimental studies." (Iakovlev Dep. [Docket 225-3], at 352). Dr. Iakovlev's "assumption" that the force he applied by pulling on the clamps accurately represents the forces inside the human body is hardly sufficient to survive *Daubert* scrutiny. Accordingly, I **FIND** that Dr. Iakovlev's opinions based on his "stretch test" are unreliable and thus, **EXCLUDED**.

Tyree, 2014 WL 5320566, at *42–43. Therefore, I **ADOPT** my prior ruling on Dr. Iakovlev, as stated in *Tyree*, and **FIND** that his opinions related to the "stretch test" are unreliable, and thus, **EXCLUDED**.¹²

2. General Causation Opinions

BSC argues that Dr. Iakovlev lacks reliable methodology for his general causation opinions related to his review of explanted mesh as part of the Bendavid study. In preparing his expert report, Dr. Iakovlev examined over 130 mesh explants, approximately sixty percent of which were transvaginal mesh devices. (Iakovlev Report [Docket 105-1], at 3). The explanted mesh types included heavy and lightweight knitted polypropylene, GoreTex, combined designs,

¹² Although BSC does not raise this objection, I question the relevance of Dr. Iakovlev's testing because it appears he only tested BSC slings, which are not at issue in the present case.

and twenty-three¹³ samples from BSC. (*Id.* at 3–4). BSC argues that because this study was not confined to polypropylene mesh and Dr. Iakovlev provides no information on how the mesh explants were chosen, the results are irrelevant and unreliable. (BSC’s Mem. re: Iakovlev [Docket 105], at 5–6). The plaintiff contends that Dr. Iakovlev’s study is grounded in reliable methodology because he followed “standard operating procedures of St. Michael’s Hospital” and saw nerve entrapment, nerve ingrowth and degradation in 100% of the BSC explants.” (Pl.’s Resp. in Opp’n to BSC’s Mot. & Mem. of Law to Exclude the Test. of Vladimir Iakovlev, M.D. (“Pl.’s Resp. re: Iakovlev”) [Docket 129], at 12–13). In *Tyree*, I found as follows:

Dr. Iakovlev provides no information on how the mesh explants were chosen or prepared for examination. (Def.’s Mem. re: Iakovlev [Docket 226], at 5–6). Dr. Iakovlev testified that the 21 BSC samples he examined were provided by plaintiffs’ counsel. (Iakovlev Dep. [Docket 268-2], at 42). I also note, in his deposition for *Edwards*, Dr. Iakovlev further testified that he requested all available meshes for examination, but had no way of knowing what methodology the plaintiffs’ lawyers employed in providing him with the number of meshes they did. (*Id.* at 157–61). Dr. Iakovlev “has given no explanation as to whether [his] is a representative sample size or how he chose the particular explants analyzed.” *Lewis*, 2014 WL 186872, at *8. “Therefore, I have no information as to the ‘potential rate of error’ inherent in [his] observations.” *Id.* (citing *Daubert*, 509 U.S. at 594). By simply highlighting the fact that Dr. Iakovlev performed an independent analysis, the plaintiffs have not demonstrated that Dr. Iakovlev’s opinions regarding pelvic mesh explants were derived using scientific methods. Therefore, Dr. Iakovlev’s general causation opinions related to the Bendavid study are **EXCLUDED**.

Tyree, 2014 WL 5320566, at *41.

In *Edwards*, I allowed Dr. Iakovlev to testify regarding Ms. Edward’s mesh because his specific causation opinions did not present the same reliability concerns as his general causation opinions. *See* No. 2:12-cv-09972, 2014 WL 3361923, at *23 (S.D. W. Va. July 8, 2014) (“Dr.

¹³ In his expert report, Dr. Iakovlev writes that he examined twenty-three BSC samples, but in his deposition, he states he examined only twenty-one. (*See id.* at 4. *But see* Iakovlev Dep. [Docket 105-1], at 42).

Iakovlev may not testify regarding his general conclusions about mesh because his choice of samples lacks scientific methodology. However, this is not a reason to exclude his testimony about Ms. Edward's mesh, which was made after a review of her explant."'). Here, BSC seeks to exclude Dr. Iakovlev's expert opinions on mesh design, mesh deformation, and polypropylene degradation in the context of his general causation analysis based on the Bendavid study, which I have determined to be unreliable. Therefore, I **FIND** that Dr. Iakovlev's opinions on mesh design, mesh deformation, and polypropylene degradation based on the Bendavid study should be **EXCLUDED**.

3. Specific Causation Opinions¹⁴

Based on the receipt and review of Ms. Eghnayem's explanted mesh, Dr. Iakovlev also offers specific causation opinions. Dr. Iakovlev opines that

Ms. Eghnayem's mesh devices caused foreign body type reaction, chronic inflammation, degradation of the mesh, bridging fibrosis, scarring with scar plate formation, nerve entrapment, smooth muscle damage and vascular abnormalities, all of which were significant contributing factors to Ms. Eghnayem's symptoms and subsequent treatment interventions.

(Iakovlev Report [Docket 105-1] at 71). BSC argues that Dr. Iakovlev's specific causation opinions should be excluded because (1) as a pathologist, Dr. Iakovlev is not qualified to render a clinical opinion and (2) the bases for these opinions are unreliable because Dr. Iakovlev cannot make a clinical differential diagnosis. (BSC's Mem. re: Iakovlev [Docket 105], at 11–12). I address each objection in turn.

¹⁴ To the extent that BSC seeks to exclude all of Dr. Iakovlev's testimony because of the unreliability of his samples, this argument is without merit. Dr. Iakovlev may not testify regarding his general conclusions about mesh because his choice of samples lacks scientific methodology. However, that is not a reason to exclude his testimony specific to Ms. Eghnayem's mesh, which was made after a review of her explant. Therefore, BSC's motion is **DENIED** to the extent that it seeks to exclude Dr. Iakovlev's mesh design, mesh deformation, and polypropylene degradation opinions specific to Ms. Eghnayem.

a. Qualifications as a Pathologist

BSC argues that Dr. Iakovlev is unqualified to offer clinical opinions because he is a pathologist, not a urogynecologist. (*Id.* at 11). A pathologist is a clinician who provides diagnoses for patient care based on the examination of specimens they receive and relevant clinical information. *Edwards*, 2014 WL 3361923, at *24 (citation omitted). In his expert report, Dr. Iakovlev states that his “professional activities include diagnostic examination of specimens surgically removed from human patients” where his “annual practice volume amounts to 5000 cases.” (Iakovlev Report [Docket 105-1], at 2). Dr. Iakovlev describes himself as an “academic physician” who “pursue[s] research endeavors and teach[es] medical students and residents.” (*Id.*). BSC does not question Dr. Iakovlev’s pathology credentials; rather, it only argues that as a pathologist, he is unqualified to render these opinions. However, throughout these MDLs, I have allowed numerous pathologists to testify regarding the properties of polypropylene mesh. *See, e.g., Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *19–20 (S.D. W. Va. Sept. 29, 2014) (discussing Dr. Richard W. Trepeta); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 621 (S.D. W. Va. 2013) (discussing Dr. Bernd Klosterhalfen). In fact, in *Edwards*, I determined that Dr. Iakovlev was qualified to render opinions specific to that plaintiff’s mesh based on his experience as a pathologist. *See Edwards*, 2014 WL 3361923, at *24–25. Therefore, I **FIND** that Dr. Iakovlev is qualified to offer specific causation opinions regarding Ms. Eghnayem based on his pathological examination of her mesh explants.

b. Reliability

Finally, BSC contends that Dr. Iakovlev’s specific causation opinions are unreliable because he “admits” that he is unable to make a clinical differential diagnosis. (BSC’s Mem. re:

Iakovlev [Docket 105], at 12). BSC mistakenly objects to Dr. Iakovlev's failure to act as a clinician, when a clinician is not what Dr. Iakovlev purports to be. A reliable differential diagnosis is typically performed after a physical examination of the patient. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999). Pathologists do not perform physical examinations or base their conclusions on them. Instead, Dr. Iakovlev explains that he performed a "morphological differential diagnosis." (Iakovlev Dep. II [Docket 105-3], at 153). Morphology is the study of human tissue and morphological findings provide basis for clinical symptoms. (Iakovlev Dep. [Docket 128-1], at 633). In preparing his expert report specific to Ms. Eghnayem, Dr. Iakovlev reviewed Ms. Eghnayem's clinical records and examined two specimens of her explanted mesh to make morphological findings that explain her symptoms. (*See* Iakovlev Report [Docket 105-1], at 69; *see also* Iakovlev Dep. II [Docket 105-3], at 152). Additionally, Dr. Iakovlev relied on clinical colleagues to provide clinicopathological correlation and rule out alternative causes. (*See* Iakovlev Dep. II [Docket 105-3], at 164, 643). Reviewing Dr. Iakovlev's report and deposition testimony as a whole, I find that Dr. Iakovlev based his opinions in large part on reliable pathology methods. He reviewed clinical records, examined explanted specimens, considered possible causes of pain, and came to a diagnostic conclusion. Challenges as to the accuracy of Dr. Iakovlev's diagnostic conclusion are better suited for cross-examination. Thus, I **DENY** BSC's motion to exclude Dr. Iakovlev's specific causation opinions.

In conclusion, BSC's Motion to Exclude the Testimony of Dr. Iakovlev [Docket 104] is **GRANTED IN PART** and **DENIED IN PART**.

K. Motion to Exclude the Testimony of Konstantin Walmsley, M.D.

BSC seeks to exclude the opinions of Dr. Konstantin Walmsley. Dr. Walmsley is a urologist who “specializes in the evaluation and management of pelvic organ prolapse, urinary incontinence, and voiding dysfunction in women.” (Walmsley Report re: Betancourt [Docket 110-1], at 1).¹⁵ Dr. Walmsley offers general opinions on the suitability of BSC’s Pinnacle device for treatment of POP. Additionally, Dr. Walmsley provides case reports specific to Plaintiff Juana Betancourt and Plaintiff Mania Nunez. First, BSC argues that the court should exclude Dr. Walmsley’s general opinions because he is unqualified to make them, particularly Dr. Walmsley’s opinions on (1) polypropylene design, testing, and warnings; and (2) the properties of polypropylene mesh. (BSC’s Mem. of Law in Supp. of Its Mot. to Exclude the Ops. & Test. of Konstantin Walmsley, M.D. (“BSC’s Mem. re: Walmsley”) [Docket 110], at 6–8). BSC also asserts that Dr. Walmsley’s general opinions on “persistent life-altering complications” and safer alternatives to mesh are unreliable. (*Id.* at 8–11). Next, BSC seeks to exclude Dr. Walmsley’s opinions that constitute legal conclusions or speculate on BSC’s state of mind. (*Id.* at 11–13). Finally, BSC contends that the court should exclude Dr. Walmsley’s specific causation opinions because they are unreliable. (*Id.* at 13–17). The plaintiffs state that Dr. Walmsley will not offer opinions regarding (1) polypropylene design, testing, and warnings; (2) the properties of polypropylene; (3) legal conclusions; and (4) state of mind. Therefore, BSC’s motion with regard to those opinions is **DENIED as moot**. For the reasons discussed below, BSC’s motion with regard to Dr. Walmsley’s remaining opinions is also **DENIED**.

1. Mesh Complications

¹⁵ The plaintiffs provided one expert report by Dr. Walmsley specific to Ms. Betancourt and one expert report specific to Ms. Nunez. (*See* Walmsley Report re: Betancourt [Docket 110-1]; *see also* Walmsley Report re: Nunez [Docket 110-2]). However, the reports are identical, except as to the medical history of each plaintiff. Therefore, I will refer mostly to Ms. Betancourt’s report, unless I am specifically discussing Ms. Nunez’s medical history.

First, BSC argues that Dr. Walmsley's opinions on mesh complications are unreliable because they are based solely on his personal experience rather than facts or data. (*Id.* at 8). BSC takes particular issue with Dr. Walmsley's statements regarding "life-threatening outcomes" and "life-altering complications." (*Id.* at 9 (quoting Walmsley Report re: Betancourt [Docket 110-1], at 3)). BSC contends that Dr. Walmsley has only treated five patients who suffered from the serious complications he describes and that his only other basis is the experience of colleagues. (*Id.*) While I agree that Dr. Walmsley has limited clinical experience with patients who have suffered serious and significant mesh complications, he has extensive experience with polypropylene POP repair kits generally and makes an attempt to explain the low number of patients in his deposition: "But you also have to understand that, first off, I – a lot of these patients I feel much more comfortable sending to an academic center because you want to have their problems fixed as quickly and safely as possible as opposed to having multiple surgeries." (Walmsley Dep. [Docket 141-2], at 262).

Additionally, although Dr. Walmsley's statement in his report regarding speaking with peers is vague, he also supports his opinions with citations to scientific literature. (Walmsley Report re: Betancourt [Docket 110-1], at 7–9; *see also* Walmsley Dep. [Docket 141-2], at 280–81 (noting that Dr. Walmsley cited reported literature on complication and exposure rates generally and specifically related to the Pinnacle)). Both the Abed article and Blandon article cited in Dr. Walmsley's report speak to his premise that vaginal mesh and graft materials cause persistent complications. *See* Abed, et al., *Incidence & Management of Graft Erosion, Wound Granulation, & Dyspareunia Following Vaginal Prolapse Repair with Graft Materials: A Systematic Review*, Int'l Urogynecol. J. (2011); *see also* Blandon, et al., *Complications from*

Vaginally Placed Mesh in Pelvic Reconstructive Surgery, Int'l Urogynecol. J. Pelvic Floor Dysfunct. (2009). Accordingly, I **FIND** that Dr. Walmsley's knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*.

2. Safer Alternatives

Next, BSC contends that Dr. Walmsley's opinions on safer alternatives are unreliable because he fails to cite any peer reviewed studies and "disavows" his opinions throughout his deposition. Both of BSC's contentions on this issue are misplaced. In his expert report, Dr. Walmsley cites the Nygaard article in support of his proposition that safe and effective alternatives to mesh surgery exist. (Walmsley Report re: Betancourt [Docket 110-1], at 7 (citing Nygaard, et al., *Abdominal Sacrocolpopexy: A Comprehensive Review*, AOG Vol. 104, No. 4, (2004) Additionally, in his deposition, Dr. Walmsley responds to a question about the comparable complication rates in mesh and non-mesh based repairs as follows: "I haven't seen numbers much higher than 3, 5 percent at highest for, let's say, native tissue repairs; whereas, I've seen two to three times those numbers in the *mesh literature*." (Walmsley Dep. [Docket 141-2], at 371-72 (emphasis added)); *see also Tyree, et al. v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *55 (S.D. W. Va. Oct. 17, 2014) ("Dr. Walker stated that although he did not rely on particular studies in preparing his report for this case, he read peer-reviewed literature and scientific studies on midurethral slings 'very, very frequently' in his clinical practice, which involves treating women with urologic dysfunction.").

Furthermore, peer-reviewed literature is merely one tool an expert witness can use to support his opinion. Dr. Walmsley has extensive experience performing POP procedures and has witnessed first-hand the difference in complications between polypropylene and non-

polypropylene treatments. In fact, his past experience with synthetic mesh has led him to rarely use it in his current practice. (*See* Walmsley Dep. [Docket 141-2], at 49–50 (“Q: When you say you do very little synthetic mesh, do – do you continue to use synthetic mesh as an option? A: Less and less so. I mean, I have done, for example, one case this year and last year I did between three and four.”)).

BSC’s contention that Dr. Walmsley “disavows” his opinions is a misinterpretation of his deposition testimony regarding his use of synthetic mesh products. Dr. Walmsley states that synthetic mesh can be a viable option in a very narrow and specific set of cases. (*See id.* at 51). For example, the benefit might outweigh the risks for an elderly patient who does not want to undergo invasive surgery and is not sexually active. (*Id.*) However, Dr. Walmsley specifically states that even in those situations, synthetic mesh is “a heroic kind of last-ditch option.” (*Id.*). Additionally, Dr. Walmsley’s discussion of the standard of care in 2008 and 2010 is based on his opinion that doctors did not have enough information about mesh products at those times to adequately warn their patients and obtain informed consent. (*Id.* at 410). Simply because Dr. Walmsley believes that polypropylene mesh devices are functional products does not mean he cannot opine that there are safer available alternatives. More importantly, because Ms. Betancourt and Ms. Nunez do not meet the narrow criteria Dr. Walmsley describes, as mentioned above, his opinions on safer alternatives are particularly pertinent to their cases. Accordingly, I **FIND** that Dr. Walmsley’s opinions on safer alternatives are sufficiently reliable under *Daubert*.

3. Specific Causation

Finally, BSC asserts that Dr. Walmsley's specific causation opinions regarding Ms. Nunez and Ms. Betancourt are unreliable because they are based solely on his "personal unscientific observations." (BSC's Mem. re: Walmsley [Docket 110], at 13).

a. Mania Nunez

The crux of BSC's argument regarding Ms. Nunez is that Dr. Walmsley opines that she will "continue[] to be plagued with complications," when her medical records do not indicate any current symptoms. (Walmsley Report re: Nunez [Docket 110-2], at 11). In opposition, the plaintiff contends that Dr. Walmsley performed a reliable differential diagnosis to come to the conclusion that mesh erosion is the cause of her pain and will continue to be in the future. Whether BSC disagrees with Dr. Walmsley's ultimate conclusion is not a sufficient basis to object under *Daubert*, given that he performed a reliable differential diagnosis. I note that, "a physician may reach a reliable differential diagnosis without personally performing a physical examination." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001). Here, Dr. Walmsley reviewed Ms. Nunez's medical records, her pathology report, and her deposition. Additionally, throughout his deposition testimony, Dr. Walmsley considers possible alternative causes of pain and subsequently dismisses them. (*See, e.g.*, Walmsley Dep. [Docket 141-2], at 437 (discussing Ms. Nunez's HPV: "In my research of the medical literature, I've not come across instances where that specific finding has been attributed to increased risk of erosion."); *see also id.* at 441 (discussing Ms. Nunez's vaginal cuff cellulitis: "Well, I understand your question and I would say yes if, in fact, the infected tissue were still present. The issue I have here is that the tissue's gone.")). Any potential errors in Dr. Walmsley's differential diagnosis "affect the weight that the jury should give the expert's testimony and not the admissibility of the

testimony.” *Westberry*, 178 F.3d at 265 (internal quotations omitted). Therefore, I **FIND** that Dr. Walmsley adequately considered and eliminated alternate causes of Ms. Nunez’s symptoms such that his differential diagnosis is reliable.

b. Juana Betancourt

BSC makes similar objections in regard to Dr. Walmsley’s opinions on Ms. Betancourt, in addition to emphasizing the fact that Dr. Walmsley’s case specific reports are mostly identical, except for the names of the patients. BSC points out that in Ms. Betancourt’s report, Dr. Walmsley failed to change the name in several places from “Martinez” to “Betancourt.” BSC argues that this typographical error is evidence that Dr. Walmsley always takes the same position “without any independent analysis.” (BSC’s Mem. re: Walmsley [Docket 110], at 14). I disagree. In his deposition, Dr. Walmsley explains his mistake:

Q: And when you saw the concerns you voiced in relation to Ms. Martinez, it looks to me like the factual statements about the injuries you have made in this – in Ms. Betancourt’s report are identical to the injuries you’ve set forth in Ms. Nunez’ report; is that correct?

A: Well, I – I don’t believe that’s fair to say, because keep in mind that the first part of my report gives a timeline that describes the injuries. And then what I start to summarize and describe my opinions, what you have to understand is a lot of these mesh-related complications do have overlap: Pelvic pain, dyspareunia, mesh erosion, mesh extrusion. Unfortunately in the case of both Ms. Martinez and Ms. Betancourt, they had a very similar spectrum of complications.

...

A: But for the purposes of this report, understand the medical records were very closely vetted by myself. I considered if there was any sort of deviations in the standard of care on the part of the doctors in terms of assessing or formulating my opinion for better, for worse, because a lot of the similar complications that I saw with Ms. Martinez, which were mesh-specific complications, that tended to be fairly redundant and reproducible element to my report.

(Walmsley Dep. [Docket 141-2], at 98–100).

Furthermore, as discussed above, it is clear that Dr. Walmsley did in fact perform an independent analysis by reviewing Ms. Betancourt’s medical records, pathology report, and deposition. Additionally, throughout his deposition testimony, Dr. Walmsley considers possible alternative causes of pain and subsequently dismisses them. (*See, e.g.*, Walmsley Dep. [Docket 141-2], at 178 (“[B]ased on my review of the medical records, I don’t see anything within the medical records that says dyspareunia pain at vaginal cuff, you know, likely hysterectomy related. This – this – these setbacks occurred over two years after the hysterectomy had been finished. So I am not of the opinion that her dyspareunia that she describes in 2012 is related to her hysterectomy.”); *see also id.* at 337 (“I don’t necessarily think that estrogen deficiency as a result of now having her body making estrogen is as relevant of an issue in the first year or two of this whole thing, if that makes sense to you.”)). Any potential errors in Dr. Walmsley’s differential diagnosis “affect the weight that the jury should give the expert’s testimony and not the admissibility of the testimony.” *Westberry*, 178 F.3d at 265 (internal quotations omitted). Therefore, I **FIND** that Dr. Walmsley adequately considered and eliminated alternate causes of Ms. Betancourt’s symptoms such that his differential diagnosis is reliable.

In conclusion, I **DENY** BSC’s Motion to Exclude the Testimony of Dr. Walmsley [Docket 109].

L. Motion to Exclude the Opinions & Testimony of Jorge Pando, M.D.

Dr. Pando, a licensed obstetrician and gynecologist, treated Ms. Betancourt after she had undergone mesh implant surgery. Dr. Pando diagnosed Ms. Betancourt “with anterior and posterior exposure of vaginal mesh and erosion,” and he performed surgery to partially remove

the mesh. (Pando Report [Docket 155-1], at ¶ 2). The plaintiffs seek to offer Dr. Pando as a “non-retained expert” to testify about his treatment of Ms. Betancourt and his opinion that “the cause of Ms. Betancourt’s pelvic pain and dyspareunia is the Pinnacle mesh and the procedure by which it is implanted as directed by Boston Scientific Corporation.” (*Id.* at ¶ 6). BSC moves to exclude the opinions and testimony of Dr. Pando on the basis that the plaintiffs did not timely designate Dr. Pando as an expert. (*See* Def.’s Mem. of Law in Supp. of its Mot. to Exclude the Ops. & Test. of Dr. Pando (“Def.’s Mem. re: Pando”) [Docket 156], at 6–7). BSC also argues that this court should limit Dr. Pando’s testimony to his care and treatment of Ms. Betancourt. (*Id.* at 7–12). Because I find that the plaintiffs did not timely disclose Dr. Pando as an expert in accordance with this court’s pretrial orders, I need not address the scope of his testimony.

Federal Rule of Civil Procedure 26 requires a party to disclose to other parties “the identity of any witnesses it may use at trial to present [expert] evidence.” Fed. R. Civ. P. 26(a)(2)(A). Furthermore, “if the witness is one retained or specially employed to provide expert testimony,” a party must accompany this disclosure with a written report detailing “a complete statement of all opinions the witness will express and the basis and reasons for them.” Fed. R. Civ. P. 26(a)(2)(B). Expert reports under Rule 26(a)(2)(B) are not required for treating physicians, *see* L.R. Civ. P. 26.1, but parties must still supply an expert report under Rule 26(a)(2)(C), stating the subject matter of the testimony and providing a summary of the witness’s opinion testimony. Fed. R. Civ. P. 26(a)(2)(C). The plaintiffs’ report for Dr. Pando satisfies the requirements of Rule 26(a)(2)(C). (*See* Pando Report [Docket 155-1], at ¶¶ 1–10 (outlining the opinions Dr. Pando is expected to offer at trial)).

Rule 26, however, also requires “a party [to] make these disclosures at the times and in

the sequence that the court orders.” Fed. R. Civ. P. 26(2)(D). This court set forth a timeline for expert discovery in Pretrial Orders # 95 and # 104. As demonstrated in the following table, the plaintiffs did not timely disclose Dr. Pando as an expert in accordance with the court’s directive.

June 9, 2014	Deadline for plaintiffs’ expert reports (Pretrial Order # 95).
June 20, 2014 (approximately)	The plaintiffs met with Dr. Pando for the first time to discuss Ms. Betancourt’s medical record. (Pando Dep. [Docket 155-2], at 56:3–23).
July 18, 2014	Deadline for the completion of expert discovery (Pretrial Order # 104).
July 18, 2014	Deadline for the filing of <i>Daubert</i> motions (Pretrial Order # 95).
July 22, 2014	Deposition of Dr. Pando (Pando Dep. [Docket 155-2], at 1).
July 25, 2014	Deadline for filing <i>Daubert</i> briefings (Pretrial Order # 95).
July 30, 2014	Plaintiffs disclosed their Rule 26 designation of Dr. Jorge Pando as a non-retained expert. (Def.’s Mem. re: Pando [Docket 156], at 6).
August 1, 2014	Deadline for case-specific discovery (Pretrial Order # 95).

The plaintiffs provided BSC with an expert report for Dr. Pando fifty-one days after the June 9 deadline. The disclosure for Dr. Pando was therefore untimely under Pretrial Order # 95. Consequently, the plaintiffs may not use Dr. Pando as a witness at trial unless their failure to file a timely disclosure “was substantially justified or is harmless.” Fed. R. Civ. P. 37(c)(1). The Fourth Circuit has offered guidance in applying this rule:

In determining whether nondisclosure of evidence is substantially justified or harmless, we consider: (1) the surprise to the party against whom the witness was to have testified; (2) the ability of the party to cure that surprise; (3) the extent to which allowing the testimony would disrupt the trial; (4) the explanation for the party’s failure to name the witness before trial; and (5) the importance of the testimony.

Hoyle v. Frightliner, LLC, 650 F.3d 321, 329–30 (4th Cir. 2011) (internal citation omitted).

Here, weighing these considerations demonstrates that the plaintiffs’ failure to file a timely disclosure for Dr. Pando was not substantially justified and is not harmless.

First, the plaintiffs’ untimely disclosure of Dr. Pando unfairly surprised BSC. Having not received a Rule 26 disclosure for Dr. Pando, BSC prepared to depose Dr. Pando as a fact

witness, rather than an expert witness, in accordance with the parties' agreed upon schedule. (*See* Def.'s Mem. re: Pando [Docket 156], at 6 n.4). Then, at deposition, BSC questioned Dr. Pando as a fact witness, allowing the plaintiffs to "[take] the lead" and to "question[] Dr. Pando first pursuant to the parties' agreement on deposition priority for treating physicians." (*Id.*). If the plaintiffs had timely served their expert disclosure, BSC would not have approached the deposition in this manner and would have instead treated Dr. Pando as an expert witness. (*See id.* at 7 ("Had Plaintiff served her disclosure prior to the deposition, Boston Scientific would not have allowed plaintiff to take the lead . . . and do the initial examination of Dr. Pando."))).

Moreover, with timely disclosure, BSC would have had "full notice of Dr. Pando's opinions prior to deposition" and could have questioned Dr. Pando about his "inconsistent" opinions. (*Id.*). In response, the plaintiffs analogize this case to *Goldman v. Phillips & Son Drilling, Inc.*, in which the court allowed the expert to testify even though the expert report was nine days late. No. 3:13-cv-152, 2014 WL 3407066, at *3 (N.D. W. Va. July 10, 2014). *Goldman* does not assist the plaintiffs in this case, when they submitted their expert report for Dr. Pando *fifty-one* days after the deadline set forth in Pretrial Order # 95.

The next factor, the ability to cure the surprise, also weighs against the plaintiffs. The plaintiffs argue that they "cured" the surprise by "submitting the disclosure to BSC just shortly [after] the deposition and "prior to the close of discovery." (Pls.' Resp. to Def.'s Mot. to Exclude the Ops. & Test. of Dr. Pando [Docket 175], at 6). To be more precise, the plaintiffs' submitted Dr. Pando's report eight days after his deposition and one day before the close of discovery. Compared to *Goldman*, wherein the party filed the expert report one day after the deposition, *Goldman*, 2014 WL 3407066, at *3, this "cure" is not satisfactory. Furthermore, the

plaintiffs' failure to timely disclose Dr. Pando as an expert prevented BSC from timely filing a *Daubert* objection to Dr. Pando's expert testimony. (Pretrial Order # 95 (requiring *Daubert* motions to be submitted by July 18, 2014)). The plaintiffs did not attempt to cure this issue at all.

This case does not implicate the third factor in *Hoyle*. I thus move to the fourth factor, which again favors BSC's motion. In an attempt to excuse their untimeliness, the plaintiffs maintain that Dr. Pando was not available for deposition at any time prior to July 22, 2014. Even if this is true, the plaintiffs could have taken various actions to prepare BSC for Dr. Pando's expert testimony. For instance, the plaintiffs could have strategized about their use of Dr. Pando when they met with him the first time, a month before his deposition. (Pando Dep. [Docket 155-2], at 56:3). In addition, the plaintiffs could have filed a motion with the court, requesting an extension for submitting an expert report for Dr. Pando. Instead, the plaintiffs waited fifty-one days after the deadline set forth by this court to notify BSC that Dr. Pando would testify at trial as an expert for specific causation.

Finally, with respect to the fifth factor, the importance of Dr. Pando's testimony carries little weight here, considering that at least one other expert for the plaintiffs can provide specific causation opinions for Ms. Betancourt. (*See, e.g.*, Walmsley Report [Docket 110-10] (providing specific causation opinion testimony for Ms. Betancourt)); *see also Tyree v. Boston Scientific Corp.*, 2:12-cv-08633, 2014 WL 5320566, at *59 (S.D. W. Va. Oct. 17, 2014) (concluding that "Dr. Shobeiri's report is not necessarily crucial to the plaintiff's ability to be heard on the merits of her case" because another expert is available to opine on specific causation).

Under the Federal Rules of Civil Procedure and *Hoyte*, the plaintiffs' disclosure of Dr. Pando is untimely, and I find that the untimeliness is not substantially justified or harmless.

Accordingly, I **GRANT** BSC's Motion to Exclude the Opinions and Testimony of Dr. Pando [Docket 155].

IV. Plaintiffs' *Daubert* Motions

The plaintiffs move to limit or exclude the testimony of Dr. Stephen H. Spiegelberg, Dr. Stephen Badylak, Dr. Matthew F. Davies, Dr. Christine L. Brauer, and Dr. Gary L. Winn.

A. Motion to Exclude the Testimony of Stephen H. Spiegelberg, Ph.D.

The plaintiffs seek to exclude the opinions of Dr. Stephen H. Spiegelberg. Dr. Spiegelberg is a chemical engineer who has extensive experience in polymer science. In his expert report, Dr. Spiegelberg concludes that polypropylene is a safe biomaterial for use in BSC's pelvic mesh devices and polypropylene remains the state of the art for synthetic graft materials. On June 2, 2014, Dr. Spiegelberg filed a supplemental report because the deposition of Frank Zakrzewski, corporate representative for Chevron Phillips Chemical Company ("Chevron Phillips"), provides additional support for the following two opinions: (1) The Medical Application Caution in the Material Safety Data Sheet ("MSDS") for Marlex HGX-030-01 polypropylene resin has no scientific or medical basis; (2) BSC's pelvic mesh devices contain two different antioxidants; therefore, BSC mesh does not undergo oxidative degradation in vivo. (Spiegelberg Supplemental Report [Docket 111-1], at 1). The plaintiffs argue that (1) Dr. Spiegelberg's opinions regarding position statements by medical organizations; and (2) his state of mind or intent opinions related to the MSDS should be struck. (Pls.' Mem. of Law in Supp. of their Mot. to Exclude the Ops. & Test. of Stephen H. Spiegelberg, Ph.D. ("Pls.' Mem. re: Spiegelberg") [Docket 112], at 1).

I have previously reviewed the opinion testimony of Dr. Spiegelberg under *Daubert*. See *Tyree, et al. v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *60–62 (S.D. W. Va. Oct. 17, 2014). While the parties in this case have not relied on precisely the same arguments, my reasoning and conclusions from *Tyree* still govern. Furthermore, to the extent that there are differences in fact and exhibits, the court does not find them sufficiently materially.

1. Opinions Regarding Position Statements by Medical Organizations

The plaintiffs seek to exclude Dr. Spiegelberg’s references to physician organization statements promoting the safety and efficacy of polypropylene material, including those of the American Urogynecological Society (“AUGS”) and the Society for Female Urology and Urodynamics (“SUFU”). Dr. Spiegelberg writes that “this history of safe use has been recognized by leading medical organizations for the treatment of female pelvic floor disorders.” (Spiegelberg Supplemental Report [Docket 111-1], at 3).

Plaintiffs argue that Dr. Spiegelberg’s characterization and use of these statements should be excluded because Dr. Spiegelberg is unqualified and lacks reliable methodology. As I indicated previously during these MDLs, position statements are not expert opinions. *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *33 (S.D. W. Va. Jul. 8, 2014). Dr. Spiegelberg is not using his “scientific, technical, or other specialized knowledge” in making these statements. Fed. R. Evid. 702. Therefore, I will not address the admissibility of this testimony here and **RESERVE** this ruling for trial.

2. Opinions Related to Chevron Phillips’s State of Mind or Intent

The plaintiffs also seek to exclude Dr. Spiegelberg’s opinions in both his expert and supplemental report related to the MSDS created by Chevron Phillips, the company whose

polypropylene BSC used in the manufacturing of POP mesh. The plaintiffs argue that these MSDS opinions are a “backdoor attempt” to opine about Chevron Phillips’s state of mind or intent. (Pls.’ Mem. re: Spiegelberg [Docket 112], at 5). The majority of Dr. Spiegelberg’s expert report properly reviews BSC records, scientific literature, and other expert reports to come to his conclusions. Section I (Polypropylene Raw Material was Appropriate for Use in Boston Scientific’s Devices), however, crosses the line into state of mind. In *Tyree*, I ruled as follows:

Although Dr. Spiegelberg’s opinion, that the Medical Application Caution was not added for any scientific reason, could have been based on the analysis present throughout his report, instead, he specifically refers to a history of “liability concerns.” (Spiegelberg Report [Docket 215-13], at 40 (“Resin manufacturers, mindful of Dow Corning’s lawsuits involving their supply of silicone for breast implants, are often reluctant to supply raw material for medical devices based purely on liability concerns, rather than performance concerns.”)). Dr. Spiegelberg infers that Chevron Phillips added the Medical Application Caution because it was concerned with liability merely because it is his personal belief and he discovered no evidence to the contrary.

In his supplemental report, Dr. Spiegelberg reiterates his belief that Chevron Phillips “did not add the statement based on any scientific or medical *concerns* with transvaginal mesh.” (Spiegelberg Supplemental Report [Docket 215-1], at 3 (emphasis added)). He bolsters this conclusion by relying on a deposition that is both vague and unclear. Dr. Spiegelberg filed a supplemental report after reviewing the deposition of Mr. Zakrzewski. While Dr. Spiegelberg states that the deposition provides additional support for his opinions, it is in fact an unreliable source. Mr. Zakrzewski clearly indicates that he has no knowledge of who wrote the MSDS or why it was written. (*See* Zakrzewski Dep. [Docket 215-14], at 45). Dr. Spiegelberg uses the deposition to unequivocally opine that there is no scientific evidence behind the MSDS; however, Mr. Zakrzewski only states that he was not aware of any scientific testing. (*Id.* at 47). Mr. Zakrzewski’s statements are inconclusive and in no way enable Dr. Spiegelberg to infer that Chevron Phillips lacked a scientific basis in adding the caution.

While an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his opinions—assuming the opinions are otherwise admissible—Chevron Phillips’s knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. *See, e.g., In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d

531, 547 (S.D.N.Y. 2004) (“Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony . . . the question of intent is a classic jury question and not one for the experts.”) (internal quotation marks omitted); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (precluding testimony as to “the knowledge, motivations, intent, state of mind, or purposes of” a company and its employees because it “is not a proper subject for expert or even lay testimony”). Accordingly, I **FIND** that Dr. Spiegelberg’s opinions related to Chevron Phillips’s state of mind or intent associated with the MSDS should be **EXCLUDED**.

Tyree, 2014 WL 5320566, at *61. Therefore, I **ADOPT** my prior ruling on Dr. Spiegelberg, as stated in *Tyree*, and **FIND** that his opinions related to Chevron Phillips’s state of mind associated with the MSDS should be **EXCLUDED**.

Thus, the plaintiffs’ Motion to Exclude the Testimony of Dr. Spiegelberg [Docket 111] is **RESERVED IN PART** and **GRANTED IN PART**.

B. Motion to Exclude the Testimony of Stephen Badylak, M.D.

The plaintiffs seek to exclude the opinions of Dr. Stephen H. Badylak. Dr. Badylak is a medical doctor and biomaterials expert with research experience related to polypropylene. In his expert report, Dr. Badylak concludes that (1) polypropylene mesh is an appropriate implantable material to reinforce soft tissue; (2) there is no evidence that BSC’s mesh experiences any form of device failure; (3) pathologic evaluation of the mesh shows no evidence of physical fracture, deformation, failure, or polypropylene degradation; (4) BSC reasonably relied on a preclinical study in proceeding to market with the mesh; (5) BSC’s design history files are complete; (6) Type-1 polypropylene mesh is non-toxic, non-carcinogenic, and non-degradable in the body; (7) implanting the mesh transvaginally does not increase risk of infection; (8) the design and testing of the BSC devices complied with accepted industry and scientific standards; and (9)

examination of two specimens is consistent with the expected response to polypropylene material and does not evidence product defect. (Badylak Report [Docket 113-6], at 4, 8, 10–17).

On June 16, 2014, Dr. Badylak filed a supplemental report because the deposition of Frank Zakrzewski provides additional support for Dr. Badylak's opinion that the Medical Application Caution in the MSDS for the raw polypropylene material used in BSC's surgical mesh was not based upon or supported by safety concerns, scientific testing, or scientific data. (Badylak Supplemental Report [Docket 113-1], at 1).

The plaintiffs argue that (1) Dr. Badylak's opinions regarding position statements by medical organizations; and (2) his state of mind or intent opinions related to MSDS should be struck. (Pls.' Mem. of Law in Supp. of their Mot. to Exclude the Ops. & Test. of Stephen F. Badylak, D.V.M., Ph.D., M.D. ("Pls.' Mem. re: Badylak") [Docket 114], at 1).

I have previously reviewed the opinion testimony of Dr. Badylak under *Daubert*. See *Tyree, et al. v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *62 (S.D. W. Va. Oct. 17, 2014). While the parties in this case have not relied on precisely the same arguments, my reasoning and conclusions from *Tyree* still govern. Furthermore, to the extent that there are differences in fact and exhibits, the court does not find them sufficiently materially.

1. Opinions Regarding Position Statements by Medical Organizations

The plaintiffs seek to exclude Dr. Badylak's references to physician organization statements promoting the safety and efficacy of polypropylene material, including those of AUGS and SUFU. Dr. Badylak writes that "[t]his resin has a long history of safe and effective use in the body and continues to be used today." (Badylak Supplemental Report [Docket 113-1], at 3). He subsequently quotes the same position statement regarding polypropylene that Dr.

Spiegelberg references in his testimony. As discussed more fully *supra* related to Dr. Spiegelberg's expert opinions and consistent with those findings, I will not address the admissibility of this testimony here because position statements are not expert opinions. *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362264, at *33 (S.D. W. Va. July 8, 2014). I **RESERVE** these evidentiary rulings for trial.

2. Opinions Related to Chevron Phillips's Knowledge, State of Mind, and Corporate Conduct

The plaintiffs also seek to exclude Dr. Badylak's opinions in both his expert and supplemental report related to the MSDS created by Chevron Phillips, the company whose polypropylene Boston Scientific used in the manufacturing of POP mesh. The plaintiffs argue that these MSDS opinions are a "backdoor attempt" to opine about Chevron Phillips's state of mind or intent. (Pls.' Mem. re: Badylak [Docket 114], at 5). A portion of the MSDS testimony in Dr. Badylak's report, as well as all MSDS testimony in the supplemental report are almost identical to Dr. Spiegelberg's testimony. (Badylak Report [Docket 113-6], at 7 ("I have not seen any evidence to indicate the additional language was supported by safety concerns or other scientific data."); Badylak Supplemental Report [Docket 113-1], at 1, 3 ("Mr. Zakrzewski's testimony lends additional support to my opinion that the medical application statement in the MSDS for the raw polypropylene material used in Boston Scientific's surgical mesh was not based upon, nor supported by, safety concerns, scientific testing or data.")). As discussed more fully *supra* related to Dr. Spiegelberg's expert opinions and consistent with those findings, I **FIND** that Dr. Badylak's opinions related to Chevron Phillips's state of mind or intent associated with the MSDS should be **EXCLUDED**.

Thus, the plaintiffs' Motion to Exclude the Testimony of Dr. Badylak [Docket 113] is

RESERVED IN PART and GRANTED IN PART.**C. Motion to Exclude the Testimony of Matthew F. Davies, M.D.**

Plaintiff Mania Nunez seeks to limit or exclude the testimony of Dr. Matthew F. Davies because “[his] methodology and resulting opinions related to a pre-existing infectious etiology for mesh complications generally and in Ms. Nunez specifically are not based upon sufficient underlying facts and data and are not the product of reliable scientific principles and methods.” (Pl. Mania Nunez’s Mem. of Law in Supp. of Her Mot. to Limit the Ops. & Test. of Dr. Matthew F. Davies, M.D. (“Pl.’s Mem. re: Davies”) [Docket 116], at 4). Dr. Davies is a board certified physician of Obstetrics and Gynecology, as well as the director of the Division of Urogynecology and Minimally Invasive Surgery at Penn State Milton S. Hershey Medical Center. Dr. Davies’s clinical practice is focused on the treatment of women with pelvic floor disorders, and he has completed over 600 mesh-based prolapse repairs. In his expert report, Dr. Davies concludes that the plaintiff’s extrusions do not indicate a defect in the Pinnacle device and that the mesh extrusion that occurred was instead a “healing issue.” (Davies Report [Docket 115-2], at 14).

I note that Dr. Davies’s report includes multiple risk factors that he believes contributed to the plaintiff’s “improper healing.” (*Id.* at 10). Nevertheless, the plaintiff has chosen to object to Human Papillomavirus (“HPV”) as a risk factor and not one of the many others mentioned. (*See id.* (“Research has shown there are other risk factors which increase the incidence of extrusions. Such risk factors include concomitant hysterectomy especially with a T – incision, and a midline incision compared to a transverse incision at the urethrovesical junction.”); *see also id.* at 15 (“As to her third extrusion, Ms. Nunez was at that time suffering from atrophic

vaginitis and hypoestrogenism . . . The decrease in estrogen causes a weakening of vaginal tissue which also can lead to a higher risk of mesh extrusions.”); *see also id.* (“Her third extrusion was associated with atrophic vaginal changes from her surgical menopause. As stated earlier, these thinner tissues certainly place her at risk for mesh extruding thru [sic] her incision line.”)).

The plaintiff specifically challenges Dr. Davies’s opinions regarding pre-existing tissue infection related to the human papillomavirus (“HPV”) as the cause of the plaintiff’s complications. The plaintiff argues that Dr. Davies’s testimony is “based on his unfounded premise that (1) such an infection can cause mesh complications generally, (2) Plaintiff was positive for HPV at the time of her implant surgery, and (3) pre-existing HPV caused Plaintiff’s mesh complications post-operatively.” (Pl.’s Mem. re: Davies [Docket 116], at 3). The plaintiff’s motion is not organized according to the objections cited above. Instead, it cites a number of instances where the plaintiff believes Dr. Davies incorrectly testifies when the plaintiff was diagnosed with HPV. For the reasons explained below, the plaintiff’s motion is **DENIED**.

1. HPV Diagnosis

By way of brief background, on February 22, 2008, Ms. Nunez visited her primary care physician, Dr. Lugo, reporting heavy bleeding during her period and pelvic pain. (Davies Report [Docket 115-2], at 9). On May 12, 2008, Dr. Lugo diagnosed Ms. Nunez with fibroids, menorrhagia, and a rectocele. (*Id.*). Dr. Lugo referred Ms. Nunez to Dr. Salom, a specialist, to evaluate her gynecological issues and prolapse. (*Id.*). On August 27, 2008, Dr. Bratter, assisted by Dr. Salom, performed a total vaginal hysterectomy with ovary preservation and a posterior repair using Pinnacle PFR system. (*Id.*). Following her first surgery, Ms. Nunez visited her doctors at least seven times presenting with complications. (*See id.* at 10–11). On August 20,

2010, Ms. Nunez was diagnosed with HPV. (*Id.* at 11). On October 27, 2010, Dr. Mendez performed a bilateral salpingoophorectomy (removal of her ovaries) and excision of vaginal mesh. (*Id.*). Following her second surgery, Ms. Nunez visited her doctors at least six times presenting with complications. (*See id.* at 12–13). On June 19, 2012, Dr. Mendez performed an excision of a two by one centimeter portion of mesh from the posterior vagina intimately involved with the rectum. (*Id.* at 13). Following her third surgery, Ms. Nunez visited Dr. Mendez three times, presenting with no symptoms or complications. (*See id.* at 13–14).

The plaintiff argues that Dr. Davies incorrectly opines that the plaintiff had HPV in 2008 before her first surgery. The court has reviewed Dr. Davies’s expert report and deposition thoroughly, noting every reference he makes to HPV. Not once does Dr. Davies opine that the plaintiff had HPV at any time before August 10, 2010, when she was diagnosed. All of Dr. Davies’s references to HPV are accurate statements of fact based on the record.

Furthermore, I agree with BSC that the plaintiff “misconstrues Dr. Davies[’s] opinions on this matter.” (Mem. in Opp’n to Pls. Mot. to Limit the Ops. & Test. of Dr. Matthew F. Davies, M.D. (“BSC’s Resp. re: Davies”) [Docket 136], at 2). For example, the plaintiff objects to Dr. Davies’s recitation of the plaintiff’s pre-existing medical history, specifically his reference to chronic cystic cervicitis. Chronic cystic cervicitis is not HPV. In his deposition, Dr. Davies discusses HPV as a possible cause of chronic cystic cervicitis, indicating that they are not the same thing. (Davies Dep. [Docket 136-3], at 214). He also clearly states that there are other possible causes of chronic cystic cervicitis, and he cannot confirm whether or not HPV was the official cause without a diagnosis. (*Id.*).

The plaintiff also objects to Dr. Davies’s explanation of possible factors contributing to

her mesh extrusion and excision procedure. (*See* Davies Report [Docket 115-2], at 10 (“This mesh extrusion and the excision procedure it necessitated is not attributable to a defect in her Pinnacle mesh, but rather, as explained more fully below, is likely the result of a combination of factors including improper healing due to her concomitant hysterectomy, placement of the sling which was potentially too superficial, and gross vaginal infection in her incision site.”). Again, the plaintiff incorrectly emphasizes “gross vaginal infection” with the belief that this is a reference to HPV. In his deposition, Dr. Davies clarifies that the gross vaginal infection he is referring to is vaginal cuff cellulitis, not HPV. (Davies Dep. [Docket 136-3], at 238). Accordingly, I **FIND** that Dr. Davies is permitted to testify about the plaintiff’s HPV diagnosis.

2. HPV Effect on Mesh

The plaintiff objects to two statements made by Dr. Davies regarding her second surgery on October 27, 2010, which the plaintiff contends relate to the premise that HPV causes mesh complications generally:

For the second surgery (in October 2010), Ms. Nunez had ongoing viral infection in her vaginal tissue due to mild squamous dysplasia and HPV. Such a viral infection of vaginal tissue resulted in pain and dyspareunia as well as increase her risk of mesh extrusions.

Secondly, her infections with HPV and bacterial vaginosis lead to discharge, pain and dyspareunia as seen at the time of her second extrusion surgery.

(Davies Report [Docket 115-2], at 15).¹⁶ The plaintiff argues that Dr. Davies’s conclusions are unreliable *ipse dixit* opinions, which are unsupported by any testing or other reliable methodology. (Pl.’s Mem. re: Davies [Docket 116], at 5). District courts have “considerable leeway” in applying *Daubert*’s reliability factors, and a full reading of Dr. Davies’s expert report

¹⁶ It is unclear why the plaintiff chose to object to these two statements, when Dr. Davies makes additional references to HPV and the second surgery at the end of his report. Therefore, I will assume that the plaintiff objects to all references regarding the effect HPV had on the plaintiff’s second surgery.

illustrates his conclusions and methodology regarding HPV are sound. *Kumho Tire Co., Ltd. V. Carmichael*, 526 U.S. 137, 152 (1999). Dr. Davies opines that HPV weakens vaginal tissue, which in turn increases the risk of mesh extrusions. Dr. Davies's opinion is based on "(1) his observations during his twenty plus years clinical experience with mesh; (2) his knowledge based on his medical training and education; (3) his knowledge based on his research and publications on mesh based POP repair; and (4) his knowledge based on his review of the medical and scientific literature." (BSC's Resp. re: Davies [Docket 136], at 5). Additionally, Dr. Davies has ample clinical experience, having completed over 600 mesh-based prolapse repairs and has researched and written about HPV. (Davies Dep. [Docket 136-3], at 207); Davies Report [Docket 115-2], at 14). Accordingly, I **FIND** that Dr. Davies is permitted to testify about HPV infections causing mesh complications generally.

Thus, Plaintiff Nunez's Motion to Exclude the Testimony of Dr. Davies [Docket 115] is **DENIED**.

D. Motion to Exclude the Testimony of Christine L. Brauer, Ph.D.

The plaintiffs seek to exclude or limit the expert opinions of Dr. Christine Brauer. Dr. Brauer is a former FDA employee and regulatory consultant who offers opinions regarding the FDA regulatory process and BSC's regulatory activities. Plaintiffs argue that Dr. Brauer's "opinion testimony regarding: (1) the FDA regulatory scheme; (2) the FDA clearance of BSC devices at issue in this litigation; (3) BSC's Directions for Use, Patient Labeling and Patient Brochures; (4) FDA MAUDE Database and MDR Reports; (5) FDA Advisory Panel Meetings; and (6) BSC's Corporate Warning Letter" should be excluded in its entirety. (Pls.' Mem. of Law in Supp. of Mot. to Exclude, or Limit the Test. of BSC's Expert Christine Brauer, Ph.D. [Docket

118], at 1–2).

I have previously reviewed the opinion testimony of Dr. Brauer under *Daubert*. See *Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *36–37 (S.D. W. Va. Sept. 29, 2014). The parties in this case assert the same arguments regarding the admissibility of Dr. Brauer’s expert opinions under *Daubert* that I addressed in *Sanchez*. To the extent that there are differences in fact and exhibits, the court does not find them sufficiently materially. The *Sanchez* excerpts quoted below are to explicate the conclusions the court reaches on the issue of Dr. Brauer’s expert opinions:

I have repeatedly and thoroughly considered the admissibility of the FDA’s 510(k) process, and I have consistently found that the 510(k) process does not relate to safety or efficacy. *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, at 753–56 (S.D. W. Va. 2014). Therefore, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. This is consistent with prior rulings by this court. See, e.g., *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195, 2013 U.S. Dist. LEXIS 102699, at *22 (S.D. W. Va. July 23, 2013) (“The FDA 510(k) process does not go to safety and effectiveness and does not provide any requirements on its own. Basically, it has no operative interaction with state tort laws.”) (internal reference omitted); Order, *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195 (S.D. W. Va. July 1, 2013), [Docket 309], at 3–4 (“Under United States Supreme Court precedent, the FDA 510(k) process does not go to whether the product is safe and effective Because the FDA 510(k) process does not go to whether the [mesh] products are safe and effective and the 510(k) process does not impose any requirements on its own, the 510(k) process is inapplicable to this case. This evidence is excluded under Federal Rule of Evidence 402 as irrelevant, and under Rule 403 for the reasons previously stated, including the very substantial dangers of misleading the jury and confusing the issues.”); Mem. Op. & Order, *Cisson v. C. R. Bard, Inc.*, No. 2:11-cv-00195 (S.D. W. Va. June 27, 2013) [Docket 302], at 3–4 (holding that evidence regarding the 510(k) process and enforcement should be excluded under Rule 403); Mem. Op. & Order, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201 (S.D. W. Va. May 12, 2014) [Docket 223], at 1 (“This is not the first time I am confronted with determining the admissibility of evidence relating to marketing clearance under the FDA’s 510(k) process In all previous cases, I excluded all evidence relating to the 510(k) process because it does not go to the safety and efficacy of medical devices and because of the potential to mislead and confuse the jury.”). Accordingly, I **FIND** that Dr. Brauer’s opinions should be excluded in their

entirety.

Sanchez, 2014 WL 4851989, at *36–37. Therefore, I **ADOPT** my prior ruling on Dr. Brauer, as stated in *Sanchez*, and **EXCLUDE** her opinions in their entirety.

E. Motion to Exclude the Testimony of Gary L. Winn, Ph.D.

The plaintiffs seek to exclude the opinions of Dr. Gary L. Winn. Dr. Winn is a professor in Industrial and Management Systems Engineering in the Safety Management program at West Virginia University who has approximately 30 years of experience in safety, health, and training. (Winn Report [Docket 119-1], at 1). In his expert report, Dr. Winn offers opinions with regard to the nature and purpose of Material Safety Data Sheets (“MSDS”) and as to the MSDS for polypropylene used by BSC in the manufacture of its pelvic mesh products. (*Id.*). The plaintiffs argue that Dr. Winn concedes he will not be offering any relevant opinions at trial, and that his opinions should be struck entirely because (1) he is unqualified; (2) his methodology is unreliable; and (3) his opinions are impermissible legal conclusions and factual narratives speculating about Chevron Phillips’s knowledge. (Pls.’ Mem. of Law in Supp. of their Mot. to Exclude the Ops. & Test. of Gary L. Winn, Ph.D. (“Pls.’ Mem. re: Winn”) [Docket 120], at 2–4). BSC construes the plaintiffs’ motion as support for BSC’s contention that the MSDS is irrelevant, but opposes all of the plaintiffs’ arguments specific to Dr. Winn. (*See generally* BSC’s Mem. in Opp’n to Pls.’ Mot. to Exclude the Ops. & Test. of Gary L. Winn, Ph.D. (“BSC’s Mem. re: Winn”) [Docket 281]).

I have previously reviewed the opinion testimony of Dr. Winn under *Daubert*. *See Tyree, et al. v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *63 (S.D. W. Va. Oct. 17, 2014). While the parties in this case have not relied on precisely the same arguments,

my reasoning and conclusions from *Tyree* still govern. Furthermore, to the extent that there are differences in fact and exhibits, the court does not find them sufficiently materially. In *Tyree*, I ruled as follows:

In his expert report, Dr. Winn describes (1) the development of the hazard communication standard; (2) the standardization of the content of MSDSs; and (3) uses of MSDSs in the field. (Winn Report [Docket 229-1], at 3–8). Dr. Winn concludes that raw polypropylene is not hazardous based on anecdotal evidence involving other MSDSs; and therefore, the 2004 Chevron Phillips MSDS is extraneous. (*Id.* at 8–10). Although I believe that the warning provided in the MSDS is relevant, I do not believe an expert is required to discuss MSDSs generally or the issue of whether polypropylene requires an MSDS because of its hazardous nature. A narrative review of the history and development of MSDSs and who uses them in the field is not helpful to the jury. The pertinent issue is that the MSDS contained a warning (Medical Application Caution) allegedly not heeded by BSC, not that an MSDS itself existed. This warning from the supplier could have taken any form.¹⁷ Accordingly, I **FIND** that Dr. Winn’s opinions regarding MSDSs should be excluded in their entirety.

Tyree, 2014 WL 5320566, at *63. Therefore, I **ADOPT** my prior ruling on Dr. Winn, as stated in *Tyree*, and **FIND** that his opinions related to MSDSs should be **EXCLUDED** in their entirety.

V. Effect of Daubert Rulings

I emphasize that my rulings *excluding* expert opinions under Rule 702 and *Daubert* are dispositive of their admissibility in these cases, but my rulings *not to exclude* expert opinions are not dispositive of their admissibility. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule. I will take up these issues as they arise.

VI. Conclusion

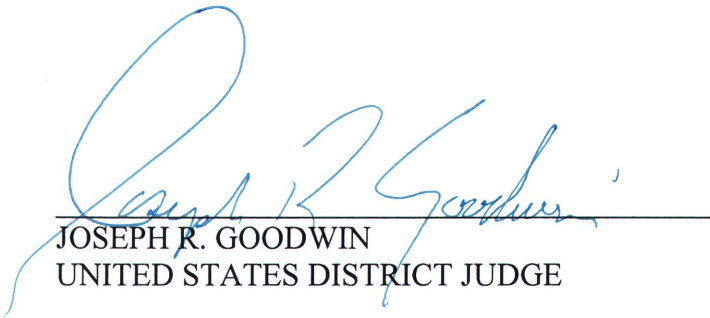
¹⁷ In fact, in another pleading, there is evidence of an agreement between BSC and its supplier indicating it was BSC’s responsibility to determine the suitability of polypropylene application. (*See* Agreement [Docket 287-6], at 3–4; *see also* Winn Report [Docket 229-1], at 10).

To reiterate: For the reasons explained below, the defendant's motion with respect to Dr. Trepeta [Docket 86] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Margolis [Docket 88] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Barker [Docket 90] is **GRANTED**. The defendant's motion with respect to Drs. Mays and Gido [Docket 92] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Salom [Docket 94] is **DENIED**. The defendant's motion with respect to Dr. Pence [Docket 96] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motions with regard to Dr. Slack [Dockets 98 and 147] are **GRANTED** and **DENIED**, respectively. The defendant's motion with respect to Dr. Raybon [Docket 100] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with respect to Dr. Kiley [Docket 102] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with regard to Dr. Iakovlev [Docket 104] is **GRANTED IN PART** and **DENIED IN PART**. The defendant's motion with regard to Dr. Walmsley [Docket 109] is **DENIED IN PART** and **DENIED AS MOOT**. The defendant's motion with respect to Dr. Pando [Docket 155] is **GRANTED**.

The plaintiffs' motion with regard to Dr. Spiegelberg [Docket 111] is **GRANTED IN PART** and **RESERVED IN PART**. The plaintiffs' motion with respect to Dr. Badylak [Docket 113] is **GRANTED IN PART** and **RESERVED IN PART**. The plaintiff's motion with regard to Dr. Davies [Docket 115] is **DENIED**. The plaintiffs' motion with regard to Dr. Brauer [Docket 117] is **GRANTED**. The plaintiffs' motion with regard to Dr. Winn [Docket 119] is **GRANTED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: October 27, 2014



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE